University of Alberta

Evaluation of Drug Policy Changes Affecting Vulnerable Populations: Stakeholder Perceptions and Drug Use Trends

by

Carlyn Iris Volume Smith ©

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment
of the requirements for the degree of Doctor of Philosophy

in

Pharmaceutical Sciences

Department of Pharmacy and Pharmaceutical Sciences

Edmonton, Alberta

Spring 2002

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled, Evaluation of Drug Policy Changes Affecting Vulnerable Populations: Stakeholder Perceptions and Drug Use Trends submitted by Carlyn Iris Volume Smith in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Pharmaceutical Sciences.

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Dedication

To my husband, Jason,

who has provided unconditional support and encouragement in all aspects of my life.

ABSTRACT

Previous studies among social services populations showed that copayments reduced drug utilization. Pal's (1997) policy evaluation framework was used to describe the process of implementation and determine the impact of Alberta Human Resources and Employment (AHRE) drug policy changes on AHRE clients, agencies, pharmacists and drug utilization. On November 1, 1997 and February 1, 1998, copayment and days supply policies were instituted, respectively. The copayment policy made adult clients responsible for a $2.00 copayment for the first three prescriptions each month. The days supply policy limited medications from 14 to 100 days supply, depending upon the medication. A unique characteristic of these policies was that AHRE included $5.00 per adult recipient in their monthly standard allowance payment. To evaluate the policy, three methodologies were used including: 1) focus group interviews with AHRE clients, pharmacists and health care and community agency representatives, 2) a mail survey of randomly selected Alberta community pharmacists, and 3) time series analysis of drug claim data for select chronic medications. The results of these qualitative and quantitative methodologies were triangulated to complete a process and impact evaluation. Process evaluation showed that only 3.1% of pharmacies had a store policy to waive the fee, and some pharmacists did evade the policy. Focus group interviews indicated that reasons for policy evasion ranged from concern regarding patients' well-being to the retention of AHRE clientele for business purposes. Pharmacists working in small, independent pharmacies were more predisposed to policy evasion than those working in large retail, grocery or chain stores. AHRE clients felt the policy was unfair. Finally, ineffective dissemination of the policy may have also impacted its implementation. The impact evaluation showed that the $2.00 copayment did not have a negative effect on the number of prescriptions, costs or defined daily dose of anti-hyperglycemics or ACE inhibitors. The combined impact of the copayment and days supply limits suggested a potentially negative impact on the defined daily dose of SSRIs. In summary, implementation of the policies was problematic; however, the policies did not seem to have significant effects on the utilization of selected classes of chronic medications.

Acknowledgements

My sincere gratitude must be conveyed to my family members who have supported me throughout this academic process. I am not certain that words will suffice to express the appreciation I feel for their unconditional encouragement. My husband, Jason, has given me love and support for the better part of my life. Most importantly, he has pushed me to question the world around me and encouraged me to develop my own voice in both my professional and personal life. I could not ask for a better partner or friend. I would also like to express my appreciation for the love and support that my mom, dad and sister, Sandy, have extended to me throughout my academic experiences and elsewhere. Special thanks also go to my "other" family - mom, dad and sister-in-law, Nadine, who served as unconditional supporters and "cheering section" these past few years.

Dr. Karen Farris encouraged me to begin this journey in higher education and has been my mentor and friend for many years. Without her guidance I would not have been in the place I am today – nor would I have been the same person. For that I am eternally grateful.

My supervisory committee deserves acknowledgement for the time they have invested in this project and me!. I must express my appreciation to Dr. K.C. Carriere who provided valuable guidance in the analysis component of this study. In addition, she never hesitated to assist me when I needed help – even if it was often. Dr. J. Church deserves acknowledgement for his input into the conceptual framework of the policy analysis, as well as for his ability to educate me on the policy implications of particular issues. Dr. Jeff Johnson provided me with valuable guidance from the conception of this

project to its conclusion. His methodological insights as well as his encouragement are appreciated more than he knows! Thanks also go to Dr. Bachynsky who served as Chair on my examining committee. He provided insight into pharmacist-specific perspectives that may have otherwise gone unnoticed. Finally, thanks must be conveyed to Dr. I. Sketris who served as the external examiner. Her thoughtful comments throughout the body of the thesis were most appreciated and she provided several insights that will assist me in my future professional endeavours.

I must extend my gratitude to Dr. E. Palylyk-Colwell and Mr. L. Shipka, employers and friends at Alberta Blue Cross, who "took a chance" on me even before this degree was completed. Their understanding and flexibility allowed me to enjoy the best of both the academic and working world – I am so grateful!

Finally, I would like to acknowledge the Alberta Pharmacy Economics Committee of the former Alberta Pharmaceutical Association and the Institute of Economics who provided funding to support this project. In addition, special thanks must be conveyed to Canada's Research Based Pharmaceutical Companies (Rx&D) who provided me with financial support through a Graduate Scholarship in Pharmacy (1998-2000).

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CHAPTER 1

INTRODUCTION

Prescription drug use and expenditures are increasing in North America. In Alberta 21.4 million prescriptions were dispensed during the year ending May 1999 at an increase of 7.7% over the previous year. The average price of a prescription was $35.64, an 8.2% increase from 1997 (IMS Health, 1999). Rising prices may be a result of three major factors including increased use of medications per capita, utilization of more expensive, new drugs and the increasing price of existing medications (Anderson & Lavis, 1994; Castonguay, Borgeat, & Champigny-Robillard, 1996; Chiles, 1995; Patented Medicine Prices Review Board, 1996). With three of four physician visits resulting in at least one prescription (Cypress, 1983) and increasing costs of newer prescription drugs, costs are a growing concern to governments and third party payers (IMS Health, 1999; Soumerai, Ross-Degnan, Avorn, McLaughlin, & Choodnovskiv, 1991).

There are several measures that may be implemented to control drug expenditures. One measure is the initiation of cost-sharing, where drug plan beneficiaries must pay a certain amount or percentage of the drug costs per prescription (Nelson, Reeder, & Dickson, 1984). Its use is based on the assertion that payment for health care or pharmaceutical agents increases individuals' accountability for health care spending decisions. In the case of pharmaceutical products, the patient would, ideally, weigh the financial costs of taking the medication with the health benefits derived from it in order to utilize necessary medications only. The decision to purchase a medication then may be partially based on the patient's price sensitivity with regard to the medication (Rubin &

Mendelson, 1996). In many cases, cost-sharing policies are combined with limits on the days supply of medications that a patient may receive (Assure, 1999; Rx Plus, 1999; Soumerai, Ross-Degnan, Fortess, & Abelson, 1993). For this reason, this manuscript will refer to cost-sharing or copayment policies assuming that they are associated with specific days supply restrictions.

Currently, there is one published peer reviewed study examining the effects of drug copayments on drug utilization in vulnerable Canadian populations. However, several studies have been conducted in the United States exploring the impact of copayments on prescription medication utilization. Each of these policies was accompanied by specific days supply limits. Six studies focused on Medicaid patients. Generally, these studies showed that cost sharing of pharmaceutical products was an effective mechanism in decreasing utilization (Angus & Karpetz, 1998; Soumerai et al., 1993). A 1993 review of the literature found that copayments as low as one dollar applied to Medicaid populations resulted in a decline of five to ten percent in overall drug utilization. There was little evidence to suggest that such copayments adversely affected patients' health status or shifted health care costs to another sector (Soumerai et al., 1993).

Despite the findings suggesting decreases in utilization with a minimum of harm to patients, there remains concerns about copayment policies. These concerns can be placed into three categories including: 1) policies are detrimental to patient populations, 2) policies are detrimental to other health care sectors and, 3) policies do not achieve their desired impact due to shifts in human behavior. The first of these concerns deals with the possible negative consequences of policies intended to control drug expenditures. Individuals faced with a copayment may decrease their use of necessary medications if they cannot afford them. For example, an individual with hypertension may decide to take a medication every second day in an effort to conserve his supply of anti-hypertensives and save money. This concern is particularly relevant in poor populations as they are more sensitive to changes in prices (Rubin & Mendelson, 1996). There is also the concern that individuals may decrease their use of essential medications while maintaining their use of those deemed non-essential when they are faced with a copayment. Patients may not be adequately informed about which medications are most critical to the maintenance of their health and may not choose to not purchase the essential medication if a choice between drugs has to be made (Nelson et al., 1984). Finally, there is the belief that individuals may be reticent about receiving medical care, such as physician visits, if the likely outcome will require the purchase of a prescription (Williamson & Fast, 1998).

The second concern of cost sharing policies is that they may increase the use of services in other sectors. Use of other medical services may increase if individuals suffer worsening of medical symptoms because of their inability to afford medications. Alternatively, individuals may actively seek out other sources of medications to receive them free or at a lesser cost (Rubin & Mendelson, 1996).

Finally, cost-sharing policies may not achieve their desired outcomes because of modification in behaviors of beneficiaries and health care professionals. Beneficiaries may intentionally or unintentionally use higher cost medical services. For example, an individual may seek treatment from an emergency room in an effort to acquire medications free of charge. An example of an unintentional behavior may be when an individual who cannot afford her medications becomes non-compliant and experiences a worsening of her disease state that causes a hospital or nursing home admission. Health care professionals may also decrease the intended impact of a policy if they waive the fee for charitable reasons or to attract future business (Rubin & Mendelson, 1996).

Alberta Human Resources and Employment (AHRE)

AHRE is a department within Alberta's Provincial government that administers the Support for Independence programs (SFI) (Government of Alberta, 1999). The goals of SFI include assisting clients in achieving independence, referring clients to other resources to help them meet their basic needs and determining eligibility and providing the appropriate level of financial and other benefits to meet clients' needs. The SFI program is in place to meet the basic needs of eligible applicants. However, this program is considered one of "last resort" where clients have exhausted all other means of supporting themselves prior to requesting assistance. SFI is considered a temporary resource that acts "as a bridge to assist clients to move towards maximum independence"(Alberta Human Resources and Employment, ongoing manual).

The monthly support payment for SFI clients includes a standard allowance that is intended for items such as food, clothing, household needs, personal needs, telephone, laundry and transportation. A shelter allowance is also included that is intended to cover the costs of accommodation to a maximum amount designated within shelter allowance policy and legislation. This amount is based, in part, on the number of family members that are dependent on the SFI client. Finally, SFI clients are also entitled to health benefits that include prescription drugs, optical, dental and other remedial treatments to ensure that SFI clients receive the goods and services necessary to maintain well-being (Alberta Human Resources and Employment, ongoing manual).

SFI clients are placed in different categories dependent on their initial assessment of need and eligibility. Table 1 lists the categories currently receiving assistance from Alberta Human Resources and Employment (Alberta Human Resources and Employment, ongoing manual).

Table 1: SFI client categories and descriptions

Client categories	Client sub-categories	Description of client categories
10		**Supplement to earnings**
	11	self-employed-developing viable business
	12	employed full-time- insufficient earnings
	13	employed part-time- insufficient earnings
20		**Employment and training support**
	21	available for work/training-receiving or waiting for EI
	22	available for work/training: minimal interactions
	23	available for work/training: moderate interactions
	24	available for work/training: long term interactions
	25	attending employment preparation: 2-12 months
	26	awaiting full-time funding from student finance
30		**Transitional support**
	31	unavailable for work/training: temporary disability/health problems
	32	unavailable for work/training: family care responsibilities
	33	unlikely to access full time employment: singles over 50 years of age
	34	child in need: living with guardian
40		**Assured Support**
	42	unable to work: severe employment barriers
90		**Assured Income for the Severely Handicapped (AISH)**
	91	Straight AISH: eligible for AISH benefits-living on their own
	92	Modified AISH: eligible for AISH benefits-living in nursing homes, auxiliary hospitals, active treatment hospitals
	93	AISH client living in government owned and operated community residence

The AHRE drug program policy

In the late 1990's, Alberta Human Resources and Employment put in place several measures to assist in cost-containment for their pharmaceutical expenditures. On

November 1, 1997 and February 1, 1998, copayment and days supply policies were instituted, respectively. Prior to these policy changes AHRE had other cost-containment mechanisms in place including the use of drug formularies, lowest cost alternatives and 100 days supply limits. Therefore the policy changes that occurred in November 1997 and February 1998 were implemented in addition to the other cost-sharing initiatives already present. The copayment policy involved adult SFI clients (≥ 18 years of age) being responsible for a $2.00 copayment for the first three prescriptions each month. The days supply limit involved a limit ranging from 100 days to 14 days supply for select medication classes. Alberta Blue Cross administers the prescription drug plans on behalf of AHRE, including the limits on days supply. The new and variable days supply limits were assigned according to criteria developed in conjunction with the Alberta College of Physicians and Surgeons, The Alberta Pharmaceutical Association, the Alberta Medical Association and Alberta Blue Cross (Alberta Human Resources and Employment, ongoing manual, accessed June 2000).

To offset patients' expense associated with prescription medications, AHRE included $5.00 per adult to each recipient on their monthly standard allowance payment. Some individuals are exempt from this copayment policy including (1) clients of the Public Trustee, (2) clients who reside in group homes, institutions or facilities where staff administer or control the administration of medications, (3) clients who receive prescription benefits through other sources (e.g., NIHB, employer benefits), and (4) medications attained through Special Authorization. Rarely, a client may be exempt due to serious physical and/or mental illness where there is reason to believe that a person may not be able to manage their resources to ensure that the appropriate medication is purchased. Days supply limits may be altered for extenuating circumstances, however, such changes require prior authorization (Alberta Human Resources and Employment, ongoing manual).

Policy Evaluation

An evaluation of the AHRE policy would allow stakeholders to assess whether the AHRE policy was functioning in practice as it was intended and whether it was achieving the desired outcomes. Policy evaluation is a mechanism to evaluate the process, impact and efficiency of a particular policy or set of policies (Pal, 1997). Evaluation has been said to involve the systematic collection of information about the activities, characteristics and outcomes of a program (Patton, 1987). Its goals are to provide feedback or information that may help to shape future policies and hopefully make improvements in them. Policy evaluation has been described as an art as it tends to utilize a variety of different methodologies in an effort to describe the effect of a policy (Majchrzak, 1984; Pal, 1997; Patton, 1987).

Policy evaluation can take three forms: impact evaluation, process evaluation and efficiency evaluation. Impact evaluation is intended to test whether or not the policy had the intended effect. Process evaluation focuses on how the policy was implemented rather than the results that were obtained by it. Finally, efficiency evaluation uses cost-benefit or cost-effectiveness analysis to describe the monetary benefits or losses of the implementation of a policy. Policy evaluations may utilize one or more of the approaches to assess a policy (Pal, 1997).

Statement of the Problem and Purpose

There is a limited amount of information about the effects of drug copayments on drug utilization in vulnerable Canadian populations. A single study consisting of interviews with people living in poverty in Edmonton suggests that these individuals perceived less access to prescription medications and health care than their wealthier counterparts (Williamson & Fast, 1998). Yet, it is unknown how the copayment policy instituted by Alberta Human Resources and Employment affected AHRE beneficiaries' drug utilization. AHRE clients may experience similar outcomes to prescription copayments as do Medicaid recipients in the United States. If this is the case, drug utilization would decline and AHRE would realize a reduction in expenditures.

The majority of studies that evaluated cost-sharing policies used the impact evaluation approach of policy evaluation (Soumerai et al., 1993). In other words, they tended to focus mainly on the outcomes or impact of the drug policy rather than the process of policy implementation and efficiency evaluation. Few researchers have examined the process of a policy's implementation. Three studies in North America have described how beneficiaries and health professionals dealt with a cost-sharing policy and their opinions of it (Fahlman, Stuart, & Zacker, 2001; Hopkins et al., 1975a, 1975b). This information is important as it forms a basis for process evaluation and creates a broader picture of the policy and its impact. Information about how a policy is implemented in the practice setting may also shed light on why a policy may or may not have achieved the desired outcome.

Thus, the purpose of this study is to describe the process of implementation and determine the impact of Alberta Human Resources and Employment (AHRE) drug policy changes on AHRE clients, agencies, pharmacists and drug utilization. This will be achieved by triangulating data from focus group interviews, surveys and analysis of drug claim data.

Research questions:

1) What are AHRE clients' perceptions of the changes in AHRE drug policy, how has it affected them and what other alternatives do they perceive to be viable to decrease drug costs in Alberta?
2) How did the changes in AHRE drug policy affect the patients, facilities and services from the perspective of employees of health care and community agencies?
3) How do pharmacists' characteristics affect their attitudes toward AHRE clients, the policy and its implementation?
4) How has AHRE drug policy affected prescription drug consumption in Alberta?

Significance

There is a dearth of information about the impact of cost-sharing policies on drug utilization in Canada. It is important to differentiate between the effects of cost-sharing policies for prescription drugs on vulnerable Canadian and American populations. Though one may infer that these policies may have similar effects in terms of decreases in drug utilization and alterations in consumer behavior, such assumptions must be confirmed because of the distinct differences between Canadian and American health care and social assistance systems.

A process evaluation of the AHRE drug policy serves several important purposes. First, little is known about beneficiaries' and caregivers' perceptions of changes in drug policy. From a government perspective, it may be important to understand what stakeholders' opinions are of the policy and its implementation. This information can serve to assist policy makers in implementing policies that address stakeholders' needs and concerns while still achieving the policy's objectives. Second, the implementation of AHRE drug policy is the responsibility of pharmacists. Pharmacies are responsible for the collection of copayments when prescriptions are filled and are also expected to ensure that AHRE clients receive the appropriate days supply of their medications. For this reason, it is important to understand how pharmacists are implementing the policy in their practice. Such information may assist policy makers in designing new implementation strategies for policies that will ensure health care professionals are compliant with the policy and its implementation is efficient. Variations in the administration of the policy or the treatment of AHRE clients may have significant impacts on the success of the cost-sharing policy.

Finally, it is important to describe the impact of the AHRE drug policy on drug utilization. As described previously, U.S. Medicaid data has suggested that cost-sharing policies have the potential to significantly decrease medication utilization. Research has also suggested that medication usage may be altered when clients are faced with a copayment for prescription drugs. For instance, individuals may choose to fill non-essential medications rather than those considered necessary to control specific conditions, thereby negatively affecting their health status. It is important to understand what effects cost-sharing mechanisms have in the Canadian context. Understanding the impact of such policies, particularly those affecting vulnerable populations may serve to inform policy makers in the future.

CHAPTER 2

LITERATURE REVIEW

Increasing expenditures on prescription medications are a growing concern for both policy makers and third party payers in Canada (Canadian Institute for Health Information 2001; IMS Health, 1999). It has been suggested that rising expenditures are a result of three major factors including increased use per capita of medications, utilization of more expensive, new drugs instead of older, less expensive medications and the increasing costs of already existing medications (Anderson & Lavis, 1994; Castonguay, Borgeat, & Champigny-Robillard, 1996; Chiles, 1995; Covari, 1998)

In response to these increases, Alberta Human Resources and Employment (AHRE) implemented a cost containment policy on November 1, 1997 that required each of its adult clients to pay $2.00 per prescription for the first three prescriptions each month. In addition, each patient was given an additional five dollars on each monthly allowance cheque. Finally, on February 1, 1998 days supply limits ranging from 14 to 100 days were placed on medications.

This review of the literature will introduce the history of social services in Canada and compare it to that of the United States. Second, cost-sharing alternatives including copayments and prescription caps will be described. Third, research that discussed policy development will assist in introducing a policy analysis framework. Finally, this framework will be used to review both process and impact evaluations of pharmaceutical cost-sharing initiatives.

A history of Social Services in Canada

Social services include various initiatives that are intended to promote health, education and well being of individuals and communities. Another term that has been used in place of social services in this context is the term "welfare services" (Hum, 1983). In order to understand the state of social services in Canada, it is important to review the history of the development of social services in this country. As well, it is useful to contrast Canada's development of social services with that of our closest counterpart, the United States, considering the majority of literature evaluating drug policy changes has emerged from that country.

In Canada, the division between provincial and federal powers is defined by the British North America (BNA) Act of 1867 (Guest, 1997; Hum, 1983). The BNA Act had a pivotal effect on the state of social services in Canada. It delegated the control of laws for the administration of justice, municipal institutions and the establishment and maintenance of prisons, hospitals, asylums and charitable organizations to the provinces. In sum, health and welfare concerns became the domain of the provinces. The federal government maintained control over sectors that were believed to be the most important to the growth of Canada and its inhabitants at that time. These sectors included commerce, interprovincial transportation, communication, immigration and other areas of economic development (Guest, 1997).

In turn, the provinces delegated much of their responsibility for the provision of social services to the municipalities. At the time the BNA Act was conceived, the philosophy of residualism, said to have emerged from the English poor laws, dominated the Canadian view of social assistance. Residualism is the belief that the responsibility for a needy individual should fall to the family first, then the church or another private organization. Only at the failure of these other safety nets did the government see fit to take some responsibility (Boychuk, 1997; Guest, 1997; Hum, 1983; Moscovitch & Drover, 1987). In addition, because there was little guidance about the provision of social services provision by the federal government, social services were administered based on the philosophical beliefs of each community (Boychuk, 1998).

In time, the need for a social services system became important as increased utilization and demand placed a greater strain on municipalities and in turn, provincial governments. Provinces were forced to become actively involved in the provision of social services. The division of power created by the BNA Act ensured that provinces had neither the taxation power nor the funding from the federal government to adequately support a comprehensive social assistance program. Often, provinces were forced to request assistance from the federal government when the financial need emerged (Boychuk, 1997; Guest, 1997; Hum, 1983).

The lack of federal involvement further encouraged diversity of provincial programs, with each province providing different modes of social assistance. For example, Quebec, Saskatchewan and Prince Edward Island took a pure form of residualism and believed that state responsibility for assisting its inhabitants was quite limited. In contrast, Nova Scotia and New Brunswick had a more involved approach and accepted responsibility for the poor, but only those who were willing to work and bear the stigmatization of receiving assistance (i.e., the deserving poor). Ontario, Manitoba, Alberta and British Columbia also designated categories of recipients as deserving or undeserving. By categorizing individuals in this manner, the provincial governments were able to administer programs and services for individuals very differently. For example, Manitoba accepted no responsibility for recipients it deemed as undeserving, whereas Alberta accepted a minimal amount of responsibility for these individuals. Ontario, British Columbia and Alberta would accept responsibility for them but only if they were willing to work. In stark contrast to the other provinces, Newfoundland provided some minimal support to ensure well-being of both its deserving and undeserving clients without the stigma of forced work (Boychuk, 1998). The categorization of individuals as deserving or undeserving poor, created a variety of programs based on definitions of entitlement. Accordingly, social services programs within Canada were fashioned into a 'patchwork' of categories that defined the needy individuals in question.

In the 1960's several concerns about social assistance emerged including narrow definitions of who was entitled to assistance, income ceilings and eligibility restrictions in each province (Hum, 1983). These issues culminated in the development of the Canadian Assistance Plan (CAP) in 1966 (Boychuk, 1997; Guest, 1997; Hum, 1983). CAP served to consolidate the Old Age Assistance (1927), the Blind Persons' Allowances (1951), the Disabled Persons' Allowances (1954) and Unemployment Assistance (1956). It also brought funding programs for needy mothers and widows under its mandate (Boychuk, 1997).

CAP required provinces to meet three conditions in order to secure cost-sharing for their social services programs. These included: 1) assistance must be provided to anyone in need, 2) there must be no provincial residency requirements and, 3) an appeal procedure must exist. Despite the intentions of CAP to try to harmonize the provision of social services across the country, provinces continued to possess diverse program characteristics. For instance, CAP required that assistance be provided to those in need but provinces were allowed to define need (Boychuk, 1997, 1998).

Criticisms of CAP suggested that it was an inadequate response to the issue of poverty in Canada (Hum, 1983). By 1977, Bill C-55 was proposed which would replace the cost-sharing component of CAP with a grant for social services programs. There were several issues at the core of this bill that prevented it from replacing CAP. First, funding was not designated specifically for social services; therefore one could not guarantee that the money would be utilized for that purpose. As well, CAP's cost-sharing arrangement ensured that the federal government would assist in absorbing expenditures. With the proposal of block funding it seemed that provinces would be forced to be responsible for any increases in social services spending. The issues surrounding this bill appeared to be unsolvable and Bill C-55 never was instituted (Boychuk, 1998; Hum, 1983).

Finally, in 1996, the Canadian Health and Social Transfer (CHST) replaced both CAP and Established Programs Financing (EPF). The CHST is block funding comprised of both cash payments and tax points for the financing of post-secondary education, health, social assistance and related social services (Guest, 1997). The implementation of CHST has been said to be evidence that the federal government had become less concerned than in the past with trying to harmonize the provision of social services across Canada. Unlike CAP, the CSHT does not place restrictions on the provincial governments to ensure a minimum standard of social assistance, however it does maintain the restriction against provincial residency requirements (Boychuk, 1998).

Key similarities between the social services systems in Canada and the U.S. do exist. Accordingly, the U.S. Medicaid system may serve as a comparator for the Canadian social services systems. First, both countries possess federal block funding of social services programs. Second, vulnerable individuals are provided financial support to ensure a minimum standard of living is met. Finally, social services recipients in each country receive both prescription medications and access to health services to ensure that they have adequate medical care (Boychuk, 1997).

Prior to using the U.S. social services system as a comparator, however, several differences between the two countries should be considered. The differences evident in the two countries are likely attributable to the differences in the historical development of the programs. The differences encompass variation in administration of the social services system, the prevalence of nationally-based programs, and the ranges of benefits and eligibility status (Boychuk ,1997).

The U.S. has adopted a more federally directed approach to administering the welfare programs than its Canadian counterpart. This is embodied by the introduction of federal social assistance legislation in 1935 as part of Roosevelt's New Deal. This legislation, called the Aid to Dependent Children (ADC) offered assistance to needy children in single parent families. In 1951, ADC was changed to Aid to Families with Dependent Children (AFDC), which broadened the criteria to include aid for one parent in a family where children are beneficiaries. One decade later, AFDC legislation was again broadened to include payments to families where both parents were unemployed. The U.S. government enacted additional legislation making the provision of social assistance homogenous across the country. For instance, the Food Stamp Act of 1964 allowed for national eligibility standards and benefit levels, even though they were administered by each state. The evolution of many U.S. federal welfare programs is in stark contrast with the Canadian government that has not yet developed any significant national programs for this population (Boychuk, 1997).

National involvement in U.S. social assistance is also evident in legislation that continues to guide each state's inclusion criteria. In Canada, the CHST has made no stipulations to the provinces about eligibility, and its only stipulation is that there be no provincial residency requirement to qualify for assistance. In Canada, social assistance is a matter of provincial responsibility in design and delivery. In addition, provinces are deemed to be fiscally responsible for its provision. In contrast, the U.S. has several stipulations that must be met before each state receives its payment. These stipulations include, for example, five-year time limits on welfare benefits, reduced spending on food stamps, work requirements after two years of receiving assistance and requirements for minimum weekly working hours. In addition, the legislation restricts federal aid to immigrants until they have resided within the U.S. for a period of five years (Boychuk, 1997).

Another difference between the two systems is that the Canadian system appears to be more generous than the American one. For example, the U.S. has enacted legislation setting maximum standards for social assistance while Canada has set neither a minimum nor maximum. In short, the combination of legislation and historical perspective has led to identifying the Canadian system as being more decentralized and generous than its U.S. counterpart. These two important differences have emerged despite the fact that there is little research indicating public support for social assistance is different in each country (Boychuk, 1997).

The final comparison of importance between Canadian and U.S. welfare systems pertains to their provision of health services. As noted previously, both countries are similar in that welfare recipients receive prescription drugs and health services. However, the manner in which health services are structured is somewhat different. Specifically, all Canadians are able to receive universal medical care which includes health services and most medications received on an inpatient basis. The coverage of prescription medications for welfare recipients is managed on a provincial level within each province's social services system (Boychuk, 1997; 1998, Naylor, 1999). In contrast, the U.S. federal government created Medicaid in 1965 which is a federal program involving cost-sharing with each state that is intended for both medical and prescription drug services for American welfare recipients (Boychuk, 1997). As part of this program, the U.S. government provided guidelines for funding prescription drug coverage to Medicaid recipients that continue today. First, prescription drugs must be provided in sufficient amounts to achieve their intended purpose. Second, medications made available for Medicaid clients may not be less in amount, duration and scope than those made available to other medically needy people. Finally, the amount, duration and scope of medication use must be the same statewide. Within the limits set by the federal government, states are entitled to control costs and limit access to prescription medications through a variety of mechanisms. These mechanisms include, for example, the use of formularies, copayments and prescription limits (Schlosberg & Jerath, 1999). Despite the fact that the Canadian government did not create a national prescription drug program for welfare recipients (Boychuk, 1997), recent evidence suggests that these individuals are well insured or covered for routine prescription drug expenditures in each province (Applied Management, 2000).

An introduction to cost-sharing

With the rising expenditures on costs of medications (IMS Health, 1999) and the increasingly important role that they play in healthcare, medication is representing a larger share of health care expenditures (Angus & Karpetz, 1998). For these reasons, pharmaceutical cost-sharing initiatives have been explored as mechanisms to substantially decrease costs to the health care system and third party payers (Rubin & Mendelson, 1996).

Cost-sharing is a type of cost-containment policy intended to increase the patient's accountability for healthcare spending decisions. Cost-sharing can be defined as "consumer exposure to out-of-pocket costs associated with health services delivery"(Rubin & Mendelson, 1996). This definition includes both direct and indirect patient exposure to costs. Direct cost-sharing includes mechanisms specifically aimed at the patient and are obviously known to him or her. Examples of direct cost-sharing measures include generic substitution, drug formularies, reimbursement rates and restricted access to specific pharmacies. Indirect cost-sharing includes those methods not necessarily noticeable to the patient and not designed to increase out-of-pocket costs, yet still able to control payer expenditures. Indirect cost-sharing may include, for example, utilization review to control the use of inappropriate medications (Rubin & Mendelson, 1996).

Generic substitution is a direct, pharmaceutical-specific cost-sharing measure that requires prescriptions be filled using the lowest cost alternative (e.g., the generic medication) to reduce pharmaceutical expenditures. An individual usually can choose whether they would prefer the generic medication or the brand name drug; however, the patient is typically responsible for the cost of the drug that exceeds the generic pricing. Finally, the use of formularies also assists in controlling medication costs. Formularies are a list of medications that are covered by the drug plan; any medications omitted from the formulary are not a benefit of the plan. Copayments are the monetary amounts that individuals, covered by prescription drug plans, are responsible for paying to receive prescription medications. For example, patients may be required to pay a certain percentage of the prescription (e.g., 10% or 25%) or they may be required to pay a flat fee to have the prescription filled (e.g, $2.00 per prescription). These methods may be used alone or in combination to assist in containing drug costs (Rubin & Mendelson, 1996).

The primary goal of cost-sharing arrangements is to increase the patient's accountability for health care expenditures. These mechanisms are purported to cause the patient to evaluate the benefit of a medication prior to purchasing it. This should cause patients to utilize only those services that may be helpful and/or necessary. In this manner, the utilization of prescription medication becomes a function of the patient's price sensitivity to prescription medication (Rubin & Mendelson, 1996).

There are three main reasons why cost-sharing mechanisms are utilized in drug plans. First, they motivate patients to reduce drug utilization. Second, they are believed to lead to more appropriate utilization. Third, they are purported to increase the efficiency of the system by creating consumers who seek the lower cost sources for their medications thereby generating revenue for the drug program (Hurley & Johnson, 1991). Accordingly, these reasons assume the cost driver of utilization is the consumer. This reasoning may be flawed, as health care professionals (e.g. physicians), usually drive costs in the health arena (Reeder, Lingle, & Schulz, 1993).

Despite the assertions about positive aspects of copayment policies, copayments have been shown to have negative impacts as well. There is evidence suggesting patients use fewer medications when faced with a copayment (Soumerai, Ross-Degnan, Fortess, & Abelson, 1993). However, there is little evidence to suggest that individuals use medications more appropriately (Reeder & Nelson, 1985; Soumerai et al., 1993). In fact, very few copayment policies in the Canadian context have been designed to increase the appropriateness of drug utilization. For example, copayments are applied to all medications so patients are responsible for the cost of the drug, independent of the type of medication chosen. This type of copayment does nothing to assist patients in making cost-effective choices, nor does it assist prescribers or dispensers to help patients make these choices (Angus & Karpetz, 1998).

If the copayment policy does not assist patients in making more effective choices about which medications to purchase, one may ask whether such mechanisms decrease only inappropriate utilization of health care services. There are several ethical and long-term expenditure repercussions that may occur if patients choose to take the non-essential medications rather than the essential ones. An example of this may be if a patient, faced with a copayment, chooses to take his hypnotic rather than his oral hyperglycemic medication (Angus & Karpetz, 1998; Soumerai, Ross-Degnan, Gortmaker, & Avorn, 1990).

Copayment policies that attempt to direct patients to utilize specific medications are becoming increasingly common, particularly in the U.S. health care system. Such a cost-sharing technique is exemplified by a 'tiered' copayment structure. For example, such policies involve assigning certain medications a lower copayment than alternative medications in an effort to encourage patients to choose the medication with the lowest copayment. A tiered copayment structure is most often implemented to encourage the use of generic medications or formulary brand medications. Tiered copayments have been shown to effectively control payer expenditures without evidence of changes in other medical resources including, for example, physician visits and emergency room visits (Motheral, 2001). One may hypothesize that a tiered copayment structure may also be effective in encouraging appropriate medication use also.

Of course, there are factors that may negate the effectiveness of the cost-sharing policy. First, site of service shifts may occur. These can be defined as intended or unintended shifts in health care from one site that requires cost-sharing to another site where cost-sharing is less or non-existent (Rubin & Mendelson, 1996). An example of one type of cost-sharing avoidance may be an individual going to the Birth Control Centre to get their oral contraceptive free of charge instead of visiting the pharmacy and being responsible for the copayment.

Another evasion of cost-sharing is changes in provider behavior that may make the policy less effective than was originally intended. For example, physicians who are aware of days supply limits may change the manner in which the prescription is written or the way a patient is supposed to take it to allow for pharmacist's discretion in assessing days supply. For example, using the instructions, take as directed, will allow the physician to write for a greater quantity and has the pharmacist being unable to assess what the appropriate days supply might be.

Finally, waiving of copayments is another means by which cost-sharing policies may be made ineffective. Copayments may be waived for charitable reasons. For example, a pharmacist may feel sorry for a patient who is required to make a copayment and may waive the fee. Alternatively, a pharmacist may waive the fee in an effort to increase future business. Word of mouth may increase business as clients inform others that this particular pharmacy does not require a copayment for prescriptions (Rubin & Mendelson, 1996).

Despite the concerns over copayments and their possible repercussions as well as the ways in which people can avoid copayments, studies have suggested that copayments are an effective mechanism for controlling prescription medication expenditures (Soumerai et al., 1993). As was stated earlier, if individuals are required to share in the cost of medications, they may make choices about the medications that they purchase. Vulnerable populations (e.g., the poor) are likely to have greater price sensitivity with respect to such cost-sharing policies. Therefore, they may feel the impact of the policy to a greater extent than would individuals with more disposable income.

A review of the process of cost-sharing policy implementation

Cost-sharing policies have been increasing in prominence in the health care sector in both Canada and the United States. Despite their prevalence, little is known about why specific cost-sharing policies are put in place and which ones policy makers believe are most effective. To examine some of these issues more closely, Soumerai et al. reported the results of in-depth, semi-structured phone interviews with 28 key informants in 19 of

22 U.S. states that changed cost-sharing policies between 1986 and 1993. Responses were elicited about their rationales for making the Medicaid policies that they did, their reservations about policy change, attempts to evaluate policy and the impact that other stakeholders, including pharmaceutical industry, government and academics, had on the process (Soumerai, Ross-Degnan, Fortess, & Walser, 1997).

There were a number of structural and political issues that contributed to the capacity of state Medicaid programs to develop and evaluate cost-sharing programs. These included policy proponents (e.g., physicians, pharmacists, advocacy groups), recurring budgetary problems, external precipitating factors, limited time for decision-making, lack of political power and lack of infrastructure for policy formulation and evaluation. Policy proponents typically included individuals who had a stake in the policy's implementation and therefore attempted to be "at the table" during a policy's formative period. Policy proponents included government officials and Medicaid program workers. Health care professionals tended to be involved in only those policies that directly affected them. For example, pharmacists became involved in medication copayment policies, because such policies could have consequences for their practice and business operations (Soumerai et al., 1997).

Recurring budgetary problems were cited as an impetus for cost-sharing policies by all of the respondents. These problems were cited as increasing medication costs, increases in total Medicaid expenditures and legislative constraints on Medicaid budgets. Other external precipitating factors included sudden budgetary crises or legislation that affected the manner in which Medicaid administered its drug plans. Of course, many of these decisions were made on tight timelines making it difficult for policy makers to develop rationales for cost-saving policies in all instances. Medicaid administrators also found they lacked authority or political power to implement the types of policies that they felt would be beneficial to all stakeholders (Soumerai et al., 1997).

The rationales for the implementation of such polices were the most indicative of the types of issues that emerged when policies were made. All respondents reported that the main policy objectives for cost-sharing strategies were to save money for the program, and others also suggested that copayments were an attempt to moderate the impact of cutbacks. Another important theme was that policy-makers believed that cost-sharing would assist beneficiaries in incorporating responsibility and rationality into their medication-taking process. Finally, three respondents believed that copayments would increase both patient and physician awareness of the inappropriate use of medications (Soumerai et al., 1997).

Individuals in states with copayment policies for prescription medications felt that several unintended negative effects had occurred with the introduction of such policies. These included reduced access to necessary medications, cost transfers to patients who could least afford it, failed drug treatment, and visits to other facilities such as emergency rooms to obtain medications. They believed these policies had particularly detrimental effects on individuals who were unfortunate enough to have several chronic medical conditions and/or require several medications on a chronic basis, though it does not appear that evaluations of their policies were conducted to assuage their fears (Soumerai et al., 1997).

Interestingly, the evaluation of such policy initiatives played a minor role in the administrators' decisions about drug policy. Although respondents were aware that prescription caps and copayments might decrease quality of care, none of their programs had been evaluated. Reasons for this phenomenon included a lack of knowledge and/or distrust of evaluation initiatives. As well, some respondents made statements that suggested they had no real grasp of the evaluation process. For example, one said that they could tell from the utilization figures that the copayments had done little to impact the health of clients. Others seemed cognizant of the importance of policy evaluation but did not have sufficient resources to carry it out (Soumerai et al., 1997).

Given the fact that the respondents were either indifferent to the importance of evaluation or suggested their resources were too limited to implement evaluation, Soumerai and colleagues asked respondents about the roles that industry, federal agencies and academic researchers played in their decisions. Most respondents felt that industry played a role in assisting with the decision-making process, whether they were acting as lobby groups or the providers of published data and short reports. Federal government appeared to play a less substantial role in the decision-making process, beyond being the ones that imposed the budget limitations that the program had to deal with. Finally, four states suggested that academic researchers were actively involved in the process of making new drug policy. The authors presented three case studies that illustrated the impact that academics had on the formulation of policy and the rebuttal of policies that may have been detrimental to stakeholders (Soumerai et al., 1997). Despite these positive comments, there were several barriers to the use of academic research in policy making. These included, lack of timeliness, perceived irrelevance of research to the problem at hand and state reliance on non-academic information sources such as Medicaid conferences. Timeliness was by far the largest issue as policymakers felt that information was not available to them in the time that they needed it (Soumerai et al., 1997).

Though this study of policy makers was conducted in the United States, it may be that Canadian bureaucrats have similar concerns and limitations in the development of their policies (Pal, 1997). In fact, the transfer of evidence into policy has been shown to be difficult in the Canadian context also (CHRSF, 1999; 2000; Lomas, 1990). The movement toward evidence-based decision making was solidified in Canada by the National Forum on Health which identified the need for decision making in the clinical and policy context to be grounded in sound evidence (CHRSF, 2000). However, as was observed in Soumerai's exploration of Medicaid policies, it is evident that there is difficulty in operationalizing the flow of evidence between researchers and policy-makers in some instances (Lomas, 1990).

The Canadian Health Services Research Foundation (CHRSF) has identified several challenges in the linkage between Canadian researchers and policy makers. From a legislative perspective, issues including poor timing of research results, lack of understanding of the process of research and the potential volatility of research findings limit the use of research in policy decisions. Policy makers' lack of expertise in research often makes it difficult to discern which decision is most appropriate when various research initiatives present competing results. Accordingly, contradicting scientific evidence can serve to undermine confidence in the research process and negatively impact the utilization of policy research in future decision-making (CHRSF, 1999).

Researchers have also been identified as being partially responsible for the lack of evidence-based decision making (Lomas, 1990; CHRSF, 1999). For instance, academic researchers traditionally have worked in isolation from current and practical policy issues and policy stakeholders (Lomas, 1990). Researchers have voiced difficulty in knowing how to access policy makers, as well as who to access, in an effort to disseminate research findings. The lack of formalized process for dissemination compounded with frequent government restructuring makes it difficult for research to always play a role during policy decision-making (CHRSF, 1999).

The development of a 'scientific culture' within Ministries, the creation of infrastructure to facilitate the dissemination of research findings and effective communication of Ministerial priorities to researchers are seen as mechanisms to help ensure that future policies are grounded in evidence (CHRSF, 1999). Increasing political accountability for decisions may begin to place higher pressure on governments to utilize research evidence (Pal, 1997).

The policy analysis framework

The process of evaluating policies has been termed policy analysis. Policy analysis is defined as the "disciplined application of intellect to public problems" and is aimed at the improvement of policies and programs (Anderson, 1987; Pal, 1997). A central question to policy evaluation is whether or not a policy is achieving the impact that was intended (Pal, 1997). There may be several reasons why a policy did not have its intended effect. Specifically, it is important to distinguish between failures of policy impact and possible failures in the policy implementation (Hogwood & Gunn, 1984). As well, it is important to note that policy analysis must deal with those issues that are under the control of the institution or governing body (Wildavsky, 1979). For example, an analysis suggesting the elimination of poverty is the means by which the health of a population may be improved is too broad a solution for policy makers to undertake.

The technical base of policy analysis is uniquely variable because of the multiple methodologies required to evaluate the variety of policies that are implemented (Pal, 1997). For this reason, researchers have developed several typologies to guide policy analysis. One typology, described by Hofferbert, divided policy analysis into three compartments that included planning aids, performance assessment and impact evaluation. Planning aids refer to the evaluation undertaken prior to a policy being conceived and implemented. This evaluation includes needs assessments, feasibility studies and participatory planning. The second area of policy analysis involves performance assessment that is meant to use methods like field reports and implementation assessments. Finally, impact evaluation uses methods including, for example, time series analysis, control group comparison and utilization review. Impact evaluation intends to ascertain if the policy had the intended effect (Hofferbert, 1985).

Another typology has been outlined as process, response and impact evaluation. The first is an evaluation of the internal workings of a policy; the second is an evaluation of the institution's responses to the surrounding environment and, finally, impact analysis evaluates the response to the policy that has been implemented (Brewer & deLeon, 1983).

A third typology has been described by Pal and includes process evaluation, impact evaluation and efficiency evaluation (Pal, 1997). Process evaluation deals with the delivery of the policy. Process evaluation is linked to the implementation of the policy and can be thought of as the evaluation of the implementation procedures. Efficiency evaluation uses cost-benefit analysis and cost-effectiveness analysis to evaluate whether the policy was economically advantageous. It focuses on resource allocation and the efficiency of particular policies, based on the theory that a policy may be effective, but not efficient, if the outcomes are achieved at too great of a financial cost (Pal, 1997).

Impact evaluation makes up only a part of the core categories of policy evaluation. Impact evaluation attempts to isolate the causes and effects of a response to a policy by using experimental and statistical methodologies to ascertain the causal relationships. Ideally, the randomized control trial would be the best mechanism to evaluate the impact of policies. However, policies are created and implemented in social and political environments that are often not conducive to the strict control that a trial would place on it. As well, policies tend to be evaluated on a retrospective basis rather than analysis plans being in place before the policy is decided upon. In the face of these shortcomings, evaluations of policies using quasi-experimental design have become increasingly popular (Pal, 1997).

Essentially, these three approaches to evaluating policy tend to be quite similar. In the comparison between Pal's and Brewer and colleagues' methodology there are two main differences. First, Pal's typology does not explicitly describe a category for evaluating the responses of the institution or government to possible external events associated with the policy (Pal, 1997). As well, the typology described by Brewer and deLeon does not explicitly allow for the evaluation of the efficiency or cost-benefits of policy implementation (Brewer & deLeon, 1983). Hofferbert extends his analysis beyond what most researchers are able to participate in by including the activities that precede the conception and implementation of a policy (Hofferbert, 1985).

The policy analysis framework outlined by Pal was chosen to frame this analysis, as it was particularly relevant to the implementation of cost-sharing policies for pharmaceuticals. There was anecdotal evidence that policy implementation may have been problematic in Alberta pharmacies; therefore, a process evaluation was viewed as playing an integral role in the evaluation. Second, impact evaluation was of primary importance in ensuring that the policy was having its desired effects.

Obviously, an ideal policy evaluation would assess all three of the components described by Pal to draw conclusions about whether the policy was effective or not. The impact and efficiency of a policy obviously depend largely on how the policy was implemented in the real world. However, it is difficult to embark on such comprehensive evaluations, often because of the sheer size of the evaluation and its associated financial costs. The realistic aspects of evaluation must be taken into account when planning policy evaluations. For this reason, program and policy evaluation has been referred to as the art of maximizing experimental control and using multiple techniques to tease out the impact of a policy (Pal, 1997).

A review of the cost-sharing literature

Literature pertaining to cost-sharing of pharmaceutical agents was accessed by completing a literature search on Medline, EMBASE and CINAHL databases using search terms including, for example, cost-sharing, cost-containment, prescription drugs, welfare, Medicaid and copayment. Articles pertaining specifically to the implementation of copayments for prescription medications in vulnerable populations, such as welfare recipients, were considered most relevant to the literature review.

There are several approaches that have been taken to evaluate pharmaceutical cost-sharing policies. The majority of the evaluations of cost-sharing policies affecting vulnerable populations involve impact evaluation. Many of these studies present the impact of the policy in terms of changes in prescription drug utilization and costs (Soumerai et al., 1993). Three manuscripts have described beneficiaries and health care professionals perceptions of cost-sharing policies as well as information on policy implementation as a means of presenting a process evaluation of a policy (Fahlman, Stuart, & Zacker, 2001; Hopkins et al., 1975a, 1975b).

The following section will discuss process, impact and efficiency evaluations of prescription drug cost-sharing initiatives on vulnerable populations in the process, impact, and efficiency framework. First, studies that conduct process evaluation of cost-containment policies will be discussed followed by impact evaluation studies. Then, studies that explore the impact of cost containment policies in other populations will be introduced. Unfortunately, a review of the literature did not reveal any efficiency evaluations dealing with pharmaceutical cost-sharing policies. Finally, two studies that utilized survey methodology to ask individuals about their hypothetical responses to cost-sharing will be reviewed to gain a better understanding of client perceptions of such initiatives.

Process evaluation of cost-sharing policies

Few studies have conducted a process evaluation of cost-sharing policies for pharmaceuticals. Four U.S. studies and one Canadian study described beneficiaries' and/or health care professionals' opinions about cost-sharing policies as well as some aspects of the policies' implementation. These studies utilized interview techniques and survey methodology to describe the policy implementation process.

A study conducted by Hopkins et al. examined the reactions of beneficiaries to the California Medicaid experiment that occurred in 1972. This policy required Medicaid clients to pay $0.50 for the first two prescriptions per month and $1.00 per outpatient visit for the first two visits per month. At the same time, beneficiaries were also required to obtain prior authorization for any prescriptions or services numbering over two per month. This study sought information about both the effects of the copayment for medical services and prescription drugs. Only the responses dealing with prescription drugs will be described in this section (Hopkins et al., 1975a).

Because of the wide number of individuals receiving Medicaid and the large geographic region that the beneficiaries covered, two counties were selected for observation. One county was considered a partly rural area, while the other was considered highly urban. 386 respondents were selected from a cohort of individuals who were continuously enrolled in Medicaid for the calendar year of 1972 as well as June 1973. Respondents were interviewed in person by research staff (Hopkins et al., 1975a).

A total of 77% of the beneficiaries reported that they were required to pay the copayment at the pharmacy. Twelve percent of beneficiaries stated that they did not pay anything for their prescriptions. From these findings, it appeared that the majority of pharmacists were implementing the policy appropriately in their practices. An important part of the implementation of cost-sharing policies is the dissemination of the policy regulations. Approximately 40% of respondents stated that the copayment policy was not clear to them, and only one-third of the families interviewed said that the policy had ever been explained to them by anyone. This finding suggests that an improvement in the policy's implementation would be the provision of more extensive information about the policy to its beneficiaries (Hopkins et al., 1975a). Although the purpose of this portion of the study was to conduct a process evaluation, beneficiaries were also asked their opinions about the impact of the policy. Twelve percent of respondents suggested that they felt the copayments had prevented them from accessing medications (Hopkins et al., 1975a).

To triangulate their findings, further interviews were completed with health care providers that included physicians, pharmacists, and employees of nursing homes and hospital outpatient departments. In particular, pharmacists employed in pharmacies that served a large number of Medicaid patients were interviewed. Ninety percent of the pharmacies were independents and ten percent were considered chain drugstores. All fifty respondents understood the intricacies of the cost-sharing policy. Ninety percent said they requested the copayment from all of their patients and reported little difficulty in collecting. Approximately one-quarter of them said that they would refuse to fill a prescription unless they were paid. Half of the pharmacists interviewed observed that there was no difference in prescription volume after the implementation of the cost-sharing policy. However, 28 percent thought that their patients were selectively filling their prescriptions and 18 percent reported that their patients delayed filling their prescriptions (Hopkins et al., 1975b).

Both of these studies provide valuable insights into the process of cost-sharing policies for prescription medications; however, there were limitations present in each of these studies. First, the findings may not reflect the process of the implementation of the copayment policy on medications alone. The prescription cost-sharing policy was also linked to a cost-sharing policy for outpatient clinic visits; therefore, it is difficult to separate the effects of each of the copayments. Second, the cost-sharing policy was also accompanied by a limit on prescription and outpatient services of two per month. Any further visits or prescriptions covered by Medicaid would have to be approved via a prior authorization process. Third, it is difficult to separate individuals' impressions about the cost-sharing and prior authorization policies. Finally, generalization of beneficiaries' reactions to the policy may be limited because respondents were not randomly selected from the initial pool of long-term users of Medicaid. Similarly, pharmacist respondents were not selected randomly, nor were a broad variety of pharmacy practitioners included. For example, only 10% of the pharmacists selected as respondents were from chain drugstores and only pharmacies with a high volume of Medicaid clientele were included. This sampling technique may have caused the study to report a more narrow perception of the policy than it would have had a more heterogeneous sample been selected (Hopkins et al., 1975a, 1975b).

Another study that examined provider reactions to cost-sharing policies for prescriptions was a survey conducted by Nelson et al, evaluating pharmacists' reactions to a South Carolina Medicaid policy that required clients to pay $0.50 for each prescription. A random sample of 200 pharmacists was mailed a 2-page questionnaire that solicited pharmacist owner/manager impressions of the program, patient receptiveness and complaints about the program. In addition, questions were included to address possible changes in physician prescribing and patient medication-taking behavior that the pharmacists may have perceived were occurring (Nelson & Quick, 1980).

These researchers attained a 91% response rate with most respondents originating from independent, traditional pharmacies. Among the responders, Medicaid clients accounted for less than 20% of their total prescription volume. Eighty-four percent of pharmacists said that there were no complaints from patients about the copayment policy, and only 7% of the pharmacists reported that their patients believed the medications should be free. Twenty-four percent of pharmacists perceived that physicians were changing their prescribing behavior by increasing quantities on prescriptions. Pharmacists also revealed their responses to the policy. Sixty-eight percent of the pharmacists said they never waived the copayment for their Medicaid patients, while 27% said that they would waive the copayment for less than 5% of their patients. Ten percent of pharmacists were aware of pharmacists who discounted the copayment for competitive purposes. Findings of importance also included the fact that all proponents who approved of the waiving the copayment were pharmacist owners and managers of independents. It was hypothesized that this finding occurred because independent pharmacies experience more pressure to waive the copayment for competitive reasons and reduce the perceived risk of losing Medicaid clientele (Nelson & Quick, 1980).

This study provides information about the behavior of health care professionals and information about the experiences of pharmacists and prescription medication copayments. A shortcoming in this study was that only pharmacy owners and managers were surveyed about their behavior and perceptions of the plan. It would have been valuable to have insights into staff pharmacists' perceptions of the plan, as they often deal with patients on a more frequent, and perhaps, more personal basis. Accordingly, they may be more concerned about the how the policy affects their patients. In addition, staff pharmacists may have different perceptions about the copayment, as they may be less concerned about the financial aspects of pharmacy operations as compared to an owner or manager.

Another study evaluated community pharmacists' knowledge and behavior in collecting Medicaid prescription copayments. A questionnaire was mailed to a random sample of 1465 pharmacists in Maryland, Pennsylvania and West Virginia. The researchers selected only one pharmacist per store and ensured that the sampling frame contained only pharmacists who were owners and/or managers. The authors noted that each of the states possessed different copayment policies. West Virginia had a sliding scale of $0.50 to $2.00 copayments with a limit of ten prescriptions per patient per month. Pennsylvania had a $1.00 copayment but certain prescription medications deemed as essential (e.g, anti-hypertensives, anti-hyperglycemic agents) were exempt from the copayment. Finally, Maryland imposed a $1.00 copayment on each medication. It was also noted that U.S. Federal law prohibits waving all Medicaid copayments. However, the law also stipulates that providers must not collect copayments if the result would be to deny access to needed therapy (Fahlman et al., 2001).

The survey was a 44-item instrument with six domains including drug store and pharmacist characteristics, estimates of Medicaid prescription volume, strategies that the pharmacists used to save clients money (this domain included waiving copayments) and circumstances in which pharmacists would collect the copayments. The response rate was 37% and the majority of respondents practiced in small town locations in independent pharmacies. Most of the pharmacists were white (90%) and male (74%) and 96% practiced full time. Results showed that over two-thirds of the pharmacies had specific policies regarding the copayment. However, it is unclear what these policies may have been. The authors suggest that the policies were to collect the copayments. Most respondents indicated that they collected the copayments for greater than 90% of the prescriptions dispensed to Medicaid clientele. Between five percent and eight percent of respondents stated that they waived the copayment for 10% or more of their Medicaid clients. Pharmacists more likely to waive Medicaid copayments practiced in stores with a high volume of Medicaid prescriptions and a large percentage of customers who were elderly Medicaid patients (Fahlman et al., 2001).

This study provides recent information about pharmacists' implementation of cost-sharing policies in pharmacies. The major limitation of this study is the accuracy in measuring the prevalence of waving copayments. Three issues may be cited for considering the results to be unreliable. First, the authors presented limited information on how the identities of respondents were maintained and how their confidentiality of their responses was ensured. If respondents had misgivings about this issue, they may have been reluctant to respond truthfully to the questionnaire due to the legal implications of admitting to waiving the copayments inappropriately. Second, the fact that only pharmacy owners and managers were asked to respond may have created an artificially low estimate of the prevalence of policy evasion. This would be because owners or managers may not regularly practice in the dispensary as a staff pharmacist would. For example, though 96% state that they work full-time, the majority of their duties may reside outside the dispensary. In addition, the selection of owners and managers made the sample skewed to white male pharmacists who may behave differently than female pharmacists or pharmacists from different ethnic or socioeconomic backgrounds. Finally, the response rate was low, making it difficult to generalize the results to pharmacies in these states. In fact, one may hypothesize that the response rate was low due to pharmacist concerns about the confidentiality of responses and the legal implications associated with responses.

The final study, completed by Tamblyn and colleagues, involved a survey of a random sample of 400 pharmacists and 400 physicians who had experience in dealing with Quebecois senior citizens and welfare recipients faced with cost-sharing policies for prescription medications. The survey measured both the providers' perceptions of the process of policy implementation, as well as the perceived impact of the policy (Tamblyn, 2001).

Pharmacists appeared to be more likely to alter their behavior in the face of the policy than physicians. For example, pharmacists chose to decrease the amount of drug dispensed or substituted less expensive medications when dispensing medications to this group of patients. Both pharmacists and physicians reported that they spend additional time with their patients both explaining the policy as well as explaining the importance of drug therapy. Pharmacists also cited a number of problems that negatively affected their practice including, for example, increasing complaints, worsening of therapeutic relationships and increasing administrative workload. Finally, pharmacists also cited that they provided store credit for individuals who were unable to afford to purchase their medications due to the cost-sharing policy.

Likely due to the fact that this aspect of the study was presented in an abbreviated nature (i.e., a case study), there was little data regarding the methods of administration of the survey and the survey instrument. In addition, limited statistical analyses of the survey results were presented. Hence, it is difficult to draw any conclusions from the data provided; however, the case study does provide some insight into the behaviors of Canadian providers when faced with cost-sharing policies for vulnerable populations that suggest this issue deserves further investigation.

Impact evaluation of cost-sharing policies for pharmaceuticals

By far the most predominant type of evaluation of pharmaceutical cost-sharing policies is impact evaluations (Soumerai et al., 1993). Impact evaluations assess the impact of copayments on variables including, for example, drug utilization, drug expenditures and hospital and nursing home admissions. Soumerai and colleagues conducted a review of the literature encompassing studies that evaluated cost-sharing policies for pharmaceuticals. The authors evaluated each study using explicit criteria including overall research design, reliability of utilization measures and adequacy of statistical analysis. The randomized control trial was considered the "gold standard" of research allowing for clear inferences about the impact of an intervention. However, this methodology is often not conducive to evaluating social policy (Soumerai et al., 1993), as rarely does a researcher have the ability to design an evaluation in the formative phases of policy development (Soumerai et al., 1997).

Therefore, Soumerai et al. selected studies with strong quasi-experimental designs such as time series with comparison series. The time series are only considered adequate if there are greater than six observation points pre and post policy implementation. These studies were considered the strongest. Partially controlled studies were also described and included studies that utilized time series without comparison groups. They found that of all of the studies that had been conducted, seven could be considered adequately controlled and interpretable. Of these seven studies, six evaluated the impact of copayments on the Medicaid population (Soumerai et al., 1993). Soumerai's method of describing and rating the studies that evaluated the impact of cost containment policies was chosen as a framework for this review because it represented a realistic means of grouping policy evaluations while taking into consideration the practical constraints associated with real life policy analysis.

Table 2 contains a description of each of the studies evaluating the impact of cost-sharing initiatives on Medicaid populations. The following section will review this literature in terms of three key findings. In addition, the limitations of these studies will be introduced. Next, a review of the only peer-reviewed study evaluating the impact of copayments on vulnerable Canadian populations will be outlined. Finally, studies that do not focus on impoverished populations will be presented to provide additional background about the perceptions and impact of cost-sharing initiatives in other patient groups.

Table 2: Review of Impact Studies

Authors	Year	Policy	Population	Methods	Outcome variables	Results
Brian EW, Gibbons SF.	1974	-$0.50 for the first two prescriptions each month - $1.00 for the first two physician's visits per month	-California Medicaid patients who possessed additional financial resources.	-survey of beneficiaries prior to and 9 months after policy implementation -survey of health care professionals concurrently with beneficiary survey - pre-post analysis of drug and health care utilization data with a non-randomized comparison group design -utilization data collected 3 months after policy implementation	-prescription drug utilization and preventative services (e.g., immunizations, Papanicolaou smears, obstetrical care, physician visits, dental services)	-prescription drug use decreased by 9.8% in the copay group and 0.7% in the non-copay group. -no significant difference in the use of essential and non-essential medications. - copayers increased their preventative medication use by only 4% while non-copayers increased by 11%

Table 2: Review of Impact Studies (cont'd)

Authors	Year	Policy	Population	Methods	Outcome variables	Results
Roemer MI, Hopkins CE, Carr L, Gartside F.	1975	-$0.50 for the first two prescriptions each month - $1.00 for the first two physician's visits per month	-California Medicaid patients who possessed additional financial resources -3 counties. -10 687 individuals in the co-pay cohort and 29 975 in the non-co-pay cohort.	-pre-post analysis with a non-randomized comparison group design (partially controlled) -data collected 6 months prior to policy implementation and 12 months after it. -compared relative rates of utilization using a common index figure of 100	- prescription utilization rates and preventative services (e.g, physician office visits, urinalysis, Pap smear, hospital patient, non-obstetrical hospital patient visits)	--prescription drugs/100 eligible patients were lower in the co-pay cohort. -both co-pay and non-co-pay cohort experienced decreases in physician visits/100 eligible patients, however, the co-pay did so at a greater rate. -hospital rates were higher in the co-pay cohort with the exception of the 3rd and 4th quarter (those immediately following the implementation of the policy)

Table 2: Review of Impact Studies (cont'd)

Authors	Year	Policy	Population	Methods	Outcome variables	Results
Nelson AA, Reeder CE, Dickson WM.	1984	-$0.50 copay for prescription medications	-17 811 South Carolina Medicaid patients subject to the copayment and 27 841 Tennessee Medicaid patients who were not subject to the copayment -counties in each state were stratified by population density, then three counties were selected from each stratum for a total of nine counties per state	-pre-post design with a control group - data collected for one year prior to the copayment and for three years after it. -Box-Jenkins ARIMA procedure used for data analysis.	-total monthly costs, number of prescription drug claims and average prescription quantity, weighted mean average cost and mean number of claims per eligible recipient were calculated.	-Pre-policy the copay group had 24.8 prescriptions/ recipient/year. Rates were 23.0, 23.6 and 24.1 years one through three post policy. -in Tennessee, there was a utilization rate of 32 prior to the policy which increased steadily from 33.2 to 37.7 in years one and three. -utilization rates decreased when the policy was implemented -mean expenditures increased in the copay group in 1976 ($133/recipient per year), declined after policy was in place ($130) and then increased to $133 and $153 in years two and three. -prescription utilization rates decreased by 0.19 more prescription/ recipient/month than Tennessee and the co-pay average monthly expenditure was also $0.48 lower than the non-copay cohort.

Table 2: Review of Impact Studies (cont'd)

Authors	Year	Policy	Population	Methods	Outcome variables	Results
Reeder CE, Nelson AA.	1985	$0.50 per prescription in the South Carolina Medicaid drug program.	-17 811 South Carolina Medicaid patients subject to the copayment and 27 841 Tennessee Medicaid patients who were not subject to the copayment -counties in each state were stratified by population density, then three counties from each stratum were selected for a total of nine counties per state	-pre-post design with a control group was used - data collected for one year prior to the copayment and for three years after it. -Box-Jenkins ARIMA procedure used for data analysis	-total monthly costs, number of prescription drug claims and average prescription quantity, weighted mean average cost and mean number of claims per eligible recipient were calculated -drugs divided into therapeutic categories (e.g, adrenergics, analgesics, psychotherapeutics, etc)	-an immediate and significant decrease in utilization was seen in all categories except analgesics and sedative/hypnotics -cardiovascular, cholinergic, diuretic and psychotherapeutic agents demonstrated a significant decrease in long term utilization in the copay group.

Table 2: Review of Impact Studies (cont'd)

Authors	Year	Policy	Population	Methods	Outcome variables	Results
Soumerai SB, Avorn J, Ross-Degnan D, Gortmaker S.	1987	limit of three prescriptions per month replaced by a $1 copayment one year later	-10,734 New Hampshire Medicaid patients (co-pay) who were continuously enrolled for 10 months in each of the four years of the study and 74, 027 New Jersey patients (non-copay)	- pre-post design with a control group -data collected for 20 months prior to policy change, for 11 months while the prescription cap was in place and 17 months after the replacement of the cap with the copayment policy.	-number of prescriptions filled, units dispensed and drug costs reimbursed - drugs divided into categories of essential, non-essential, costly and inexpensive drugs.	-cap caused an immediate and sustained drop of 46% (5.2 to 2.4 prescriptions /person/month) -after copayment replaced the cap, rates rose to 4.7 prescriptions/person/month. -prescription size increased by 11 units/prescription during the cap period then decreased by 16 units/prescription when replaced by the copayment. -number of prescriptions for effective, essential medications declined from 67.0 to 48.6 prescriptions/100 patients; for symptomatic relief from 28.3 to 17.4; for drugs of limited efficacy 5.5 to 2.3. -savings of each policy were comparable with the cap saving 0.8 million dollars and the co-pay saving 0.4 million dollars.

Table 2: Review of Impact Studies (cont'd)

Authors	Year	Policy	Population	Methods	Outcome variables	Results
Soumerai SB, Ross-Degnan D, Avorn J, McLaughlin TJ Choodnovsky I.	1991	limit of three prescriptions per month replaced by a $1 copayment one year later	-411 patients in New Hampshire (co-pay) and a matched comparison cohort in New Jersey of 1375 patients. -patients were eligible if they were over 60 years of age, were enrolled with Medicaid for 10 months or more in the baseline year, were white, living in community at baseline, had no nursing home claims in previous 6 months, took 3 or more medications per month and used medications for one or more illnesses including diabetes, heart disease, COPD, asthma, seizures or anticoagulants	-pre-post design with a control group -36 months of data were obtained -4 months prior to cap, during cap and 10 months after it was replaced by the copayment.	-hospital and nursing home admissions during the 36 month study period - standardized monthly doses of core drugs (e.g., anti-anginals, loop diuretics, anticoagulants)	-a decrease from 2.8 to 1.9 (35%) standardized monthly doses per patient per month was seen after cap was in place - after cap was replaced by copayment, drug utilization returned to normal levels. -relative risk of admission associated with the cap was 1.8 (95%CI 1.2-2.6) then returned to normal during the copayment portion. -at end of cap period 7.7% of 325 community dwelling New Hampshire patients were institutionalized compared with 4.4% of 1147 New Jersey patients.

Three key findings have emerged from the impact evaluations of pharmaceutical cost-sharing initiatives in Medicaid populations. First, prescription caps, or limits to the number of prescriptions a recipient may receive during a given time period, may be more detrimental to patients than the initiation of copayment policies. Two studies have examined this issue. Both studies were conducted by Soumerai and colleagues in 1987 and 1991, respectively (Soumerai, Avorn, Ross-Degnan, & Gortmaker, 1987; Soumerai, Ross-Degnan, Avorn, McLaughlin, & Choodnovskiv, 1991). Results from these studies suggested that copayments decreased drug expenditures and utilization to a lesser extent than prescription caps. The 1991 study examined the impact of both prescription caps and copayments on admissions and provides information that compares the two initiatives and their possible repercussions. The authors suggested that policy makers seriously consider the repercussions of cost-containment procedures for pharmaceuticals (Soumerai et al., 1991).

The second key finding was that low income populations are sensitive to cost-sharing policies and that they tend to respond to them by decreasing their utilization of medications. This finding has been substantiated by all six of the studies that evaluated the impact of cost-sharing in Medicaid populations.

The third key finding from the impact evaluations of cost-sharing techniques in low-income populations suggests that such policies decrease the utilization of both essential and non-essential medications. Three of the studies possessed components that evaluated this phenomenon. The first study was one conducted by Reeder and Nelson that evaluated the impact of a $0.50 copayment per prescription. These researchers found that there were immediate and significant decreases in all therapeutic categories except for analgesics and sedative hypnotics. As well, they evaluated the utilization of therapeutic categories over a specific period of time and found that cardiovascular, cholinergic, diuretic and psychotherapeutic agents demonstrated a significant change in long-term utilization (Reeder & Nelson, 1985).

Both the studies published by Soumerai and colleagues in 1987 and 1991 possessed a component that evaluated the utilization of specific classes of medications. The prescription cap created a reduction in the use of essential medications that ranged from a decrease of three to five prescriptions/100 patients/month. The replacement of the cap with a copayment approximately one year later increased drug utilization, however, it did not match pre-policy levels. It is unclear from the results whether the copayment created a statistically significant change from pre-cap utilization levels (Soumerai et al., 1987)

Though all of these studies are considered to be comprehensive impact evaluations of cost-sharing polices in low-income populations in the U.S., they do possess some shortcomings. Two limitations common to some of these studies should be noted. First, the study durations may not have been long enough to attribute changes in utilization to the implementation of the policy. A study too short in duration may make it difficult to discern if the change in drug use was due to the policy or some seasonal aberration that may have occurred. In an extreme case where follow-up was very short, there may simply have been no prescriptions dispensed at that time. For example, the study conducted by Brian and Gibbens has been criticized for its extremely short duration. This becomes an issue in the interpretation of the impact of the policy for several reasons. First, patients may not have had prescriptions filled during that time period therefore the effects of the policy may be underestimated. Second, seasonality may exist in utilization of prescriptions and medical services. It is possible that responses to the policy in that short time frame could not be generalized to a longer period of time. Shortly after this study was completed, Roemer and colleagues reanalyzed the data in an effort to rectify the shortcomings. Despite the fact that they did lengthen the duration included in analysis, there remained issues. In this case, Roemer et al., used data 6 months prior to the policy implementation and 12 months after it. Though 12 months post-policy may have been adequate, the pre-policy time period may have been too short to establish any specific trends in drug utilization.

The second limitation involved the difficulty in discerning the impact of other policies that were implemented at approximately the same time as cost-sharing policy. The use of a control group would likely not serve to prevent this limitation unless all policies implemented with the exception of the one under study were similar between the control and treatment groups. Little can be done to rectify this type of limitation, as the implementation of policy is most certainly beyond the control of most evaluators. The majority of the studies that evaluated the impact of the cost-sharing policy for Medicaid populations were accompanied by other policy initiatives in different sectors making it difficult to attribute utilization to cost-sharing alone. For example, two studies that analyzed the impact of the $0.50 copayment on California Medicaid clients exhibited this limitation (Brian & Gibbens, 1974; Roemer, Hopkins, Carr, & Gartside, 1975). This drug policy was accompanied by a policy that required patients to pay $1.00 for the first two outpatient visits per month. As one might imagine, the receipt of prescriptions is inextricably linked to physician visits. If beneficiaries were not able to afford visits to physicians, prescription claim volumes may experience a natural decrease regardless of whether there was a copayment required for the medication itself. As well, a special authorization policy that allowed for an increased number of visits and/or prescription for select clients that was put in place two months prior to the policy's implementation, further convoluted the findings. It is difficult to draw exact conclusions about what impact the prescription medication copayment had on medication utilization.

An impact evaluation in vulnerable Canadian populations

One study examining the effect of copayments on vulnerable Canadian populations was recently published in the peer-reviewed literature. Specifically, this study examined the effect of a cost-sharing policy on the use of essential and non-essential drugs and rates of emergency room visits and serious adverse events on both the elderly and welfare populations.

Prior to 1996, Quebec's welfare recipients and low-income seniors received free medication and all other elderly individuals were required to pay $2.00 per prescription. In August 1996, the policy was revised so that welfare recipients were required to pay a 25% copayment on each of their prescriptions up to a maximum of $200. Elderly individuals were required to pay the same copayment up to a variable maximum of $200, $500 and $750, depending on income. In January 1997, an annual deductible of $100 was added to the policy and in July 1997, the copayment and deductible were prorated so that individuals would not be required to pay a large amount per month (Tamblyn et al., 2001).

Tamblyn and colleagues identified select medications as essential or non-essential medications. Drug use was measured at monthly intervals for a random sample of both welfare and elderly recipients at an individual level. Of those randomly sampled for participation in the study, 55,333 adult welfare patients and 93,950 elderly patients met study criteria. Interrupted time series analysis was utilized to examine the impact of the policy on utilization. Findings indicate the policy created a significant reduction of 9.14% (95%CI 8.8% to 9.5%) in overall number of prescription drugs used per day by elderly recipients and a decrease of 15.84% (95%CI 15.0% to 16.9%) for welfare patients. The use of essential medications was also affected by the policy with a 9.12% (95%CI 8.7% to 9.6%) decrease for elderly individuals and a 14.4% (95%CI 13.3% to 15.6%) decrease for welfare patients. Non-essential medications experienced a greater decrease in utilization than essential medications with the elderly experiencing a 15.14% decrease (95%CI 14.4% to 15.9%) and welfare patients experiencing a 22.39% decrease (95%CI 20.9% to 23.9%) (Tamblyn et al., 2001).

In addition, pre and post policy cohort studies were utilized to examine the rates of adverse events and emergency department visits that could be attributed to the policy. The pre-policy period was used to provide an estimate of the expected rate of adverse events due to a reduction in the use of medications. The difference in the rate of event occurrence between pre and post policy periods was used to estimate the impact of the policy on the events. Results suggested that there was a significantly higher rate of adverse events as well as emergency room visits for individuals who decreased their use of essential medications. Specifically, the rate of serious adverse events per 10 000 person-months related to decreases in essential medications increased from 5.8 to 12.6 in elderly patients and from 14.7 to 27.6 in the welfare recipient group. The rate of emergency room visits increased from 32.9 to 47.1 for elderly patients and 33.5 to 74.8 in the welfare recipient group. The authors concluded that the cost-sharing policy created a decrease in the number of essential medications patients received which, in turn affected the rates of serious adverse events and emergency room visits (Tamblyn et al., 2001).

This study possessed several strengths. First, uniquely identifiable individual data was utilized which allowed the researchers to investigate not only trends in drug utilization, but associated outcomes including adverse events and emergency room visits. Though the outcome data examined in this study does not directly measure the impact that cost-sharing polices have on the health status of populations, it may be a surrogate indicator for how these policies may affect the health of patients. Second, this study provides an analysis of the impact of cost-sharing policies for pharmaceuticals in the Canadian population. Previously, there was no information in the peer-reviewed literature that examined the impact of such policies on Canadians. Finally, this study examined the impact of cost-sharing polices on essential and non-essential medications in an effort to examine whether patients would choose to become non-compliant with one class or another. This is important as many critics of cost-containment policies for pharmaceuticals assert that the use of both essential and non-essential medications is often affected by such policies (Soumerai et al., 1993). This study supports that assertion and links the decline in utilization of essential medications to other outcome variables.

Perhaps the greatest limitation this study possesses is the lack of comparison group. As identified by Soumerai (Soumerai et al., 1993), the strongest quasi-experimental design for evaluating such policies would require a comparison series in order to ensure that changes in utilization or other outcome variables can be attributed to the policy. However, the authors assert that no other explanation for such a dramatic decline in utilization could be identified.

Second, Tamblyn and colleagues used published criteria and expert opinion to define medications as essential or non-essential. Because many medications have a variety of indications, limitations arise if a medication is incorrectly classified for an individual. For example, medications considered non-essential such as a benzodiazepine, could be used for a necessary indication; therefore, this nuance would not be captured in this analysis.

Patients may also have obtained medications via difference mechanisms that could not be captured by this analysis. For example, physicians may have provided patients with samples where possible so that patients were not subjected to the copayment. Such medication use behavior would artificially lower the prescription drug utilization evident in the results.

In addition, little information is provided about the context in which the policy was implemented and whether there were other factors that may have affected the utilization measures. For example, if health care restructuring were occurring patients may increase their visits to emergency rooms or physicians and the utilization of these services would be artificially increased.

Finally, Tamblyn and colleagues do not provide any insight into beneficiaries' behaviors during the study period that may have occurred in response to cost sharing. Interviews or surveys administered to patients may have provided additional information about the implementation of the policy as well as patient medication use behaviors.

Impact evaluation in other populations

Evaluations of the impact of cost-sharing policies have also been conducted in other patient populations. The results of these evaluations appear to support the key findings of impact evaluations of cost-sharing policies in low-income populations. Two examples of evaluations in other populations are given to illustrate that other populations may also be sensitive to increases in out-of-pocket expenses for medications.

The finding suggesting that cost-sharing decreases drug utilization was supported by a study conducted by Harris and colleagues that evaluated the effect of the implementation of a copayment on members of a heath maintenance organization. This study examined the drug utilization of 19 982 continuously enrolled beneficiaries during a period of changing drug copayments ranging from $1.00 to $3.00. A group of approximately 23 000 people who did not experience cost-sharing initiatives were used as a comparison group. The initial implementation of a $1.50 copayment showed a decrease of 10.7% in prescription drug utilization relative to the comparison group. Increasing levels of copayment continued to have statistically significant effects on drug utilization. For example, the $3.00 copayment was associated with a further decrease of 10.6% in utilization and the $3.00 copayment plus additional cost-sharing measures resulted in an additional 12% decrease. The authors concluded that cost-sharing of prescription medications was an effective means of controlling drug use in an HMO without adversely affecting patient outcomes or increasing the use of other health care services (Harris, Stergachis, & Ried, 1990). It is important to note that this study was conducted on beneficiaries of a health maintenance organization that were receiving drug benefits from their place of employment. The results of this study cannot be generalized to sicker, older or poorer populations. However, it is interesting to note that even individuals with a steady income may be sensitive to nominal copayment policies.

A second study conducted by Leibowitz et al. focused on the demand for medications as a function of cost-sharing using data from the RAND Health Insurance Experiment (HIE) in the United States. In this study, the HIE randomly assigned families to insurance plans with varying coinsurance rates and deductibles. Cost-sharing was independent of demographic and health characteristics and no choice of plan was offered to participants. One third of the participants were assigned to a zero coinsurance rate, one-fifth were required to pay 25% for medical services to an upper limit of 5, 10, or 15% of last year's income or $1000 whichever was less. One-twelfth of the families faced a 50% co-insurance rate subject to the previously mentioned cap. Finally, one-fifth of the sample was subject to 95% co-insurance of the cost of medical services up to an annual limit of $150 per person or $450 per family. All prescription medications were included in the plan and over-the-counter medications were covered if a prescription was written for them. The authors found that individuals with more comprehensive insurance purchased more prescription medications. For example, individuals with total coverage purchased 5.43 prescriptions per capita, while those who were responsible for 95% of the costs utilized 4.3 medications per capita. The response to medication cost-sharing was similar to that of medical services (Leibowitz, Manning, & Newhouse, 1985).

As with studies that evaluated the impact of cost-sharing policies on Medicaid clients, they also shared some limitations. First, the study conducted by Leibowitz and colleagues evaluated the cost-sharing of both medical care and prescription services, therefore it was difficult to separate the effects of the medical care copayment and the prescription copayment. For example, individuals with a more restrictive plan may have avoided seeing physicians because of prohibitive costs, thereby not receiving prescriptions for necessary indications. Despite this shortcoming, the study does offer some valuable information about patient behavior when faced with cost-sharing of medical care and prescription drugs (Leibowitz et al., 1985).

One study departs from the key findings that have been reported in the impact evaluations of cost-sharing policies. It should be noted that this study was not peer-reviewed. This study was conducted in Quebec and evaluated the effect of a $2.00 copayment on prescription renewal rates of elderly Quebecois. The study population comprised residents over the age of 65 years who had at least one claim for anti-hypertensive medications or benzodiazepines from January 1991 to April 1992. Individuals who received medication for greater than 181 days and less than 21 days were excluded from the study. Finally, individuals were included who lived within the postal codes that had average incomes between $13 000 and $20 000 and greater than $45 100. This was completed to exclude individuals with a low enough income to receive a guaranteed income supplement. Rates were expressed as a proportion of the days in which the patient had medication during the observation period. Despite the concerns voiced by pharmacists and other health care providers about the possibility of non-essential medications being chosen over essential medications in response to the policy's implementation, this finding was not observed. It appeared that elderly, regardless of whether they were considered high or low income, remained compliant with essential medications. Therefore, in contrast to the other evaluations, the authors concluded that the $2.00 copayment had no impact on either the medication type or income category (Poirer, LeLorier, Page, & Lacour, 1998).

Impact evaluations of pharmaceutical cost-sharing policies have been conducted on various populations. In general, it has been found that prescription caps may be more detrimental than copayments, individuals may be sensitive to prescription copayments and both the use of non-essential and essential drugs may decrease.

Surveys of client reaction to hypothetical situations

Another manner in which researchers have tried to ascertain how copayments affect medication use is survey methodology. Two studies used surveys to ask respondents how different levels of copayments would affect their medication consumption. In the first study, 8000 inhabitants of Sweden were surveyed and asked whether or not their medication use would change if they were responsible for a copayment. The researchers varied the hypothetical copayment between 9 and 150% of the prescription cost. Results showed that price sensitivity decreased with age, income, education and self-rated health status. In addition, the researchers asked respondents how a copayment might affect their utilization of specific types of medications. Price sensitivity was highest for antitussives and lowest for climacteric medications (e.g., hormone replacement therapy). For example, if user charges doubled, only 11% of hormone replacement medication users would reduce their consumption, whereas 40% of antitussive users would decrease their use of these medications. The authors concluded that individuals who are young, have poor health status, low education and low incomes were more likely to decrease consumption of medications when user charges were put in place (Lundberg, Johannesson, Isacson, & Borquist, 1998). Their findings about the effect of age on price sensitivity is contrary to what other researchers have found as they have described elderly as being more price sensitive (Soumerai et al., 1987; Soumerai et al., 1991). The authors of this study suggest that this may be because they controlled for other demographic factors such as education and income, while Soumerai and colleagues did not (Lundberg et al., 1998).

Stuart et al., used a survey methodology to ask the opinions of 4,066 elderly Pennsylvanians to analyze the relationship between ability to pay and medication decisions. It was found that elderly persons with Medicare supplements were between 6 and 10 % more likely to use prescription medications to treat their health conditions than individuals without coverage. Income was also shown to have a strong and independent effect on medication decisions. For example, elderly with an income of greater than $18,000 annually were more likely to treat problems with prescription drugs than individuals with annual incomes of less than $6,000. These authors concluded that medication use in elderly populations was dependent on economic factors, therefore individuals who are poor and lack drug coverage may be at greater risk of negative consequences (Stuart & Grana, 1998).

Obviously, the previous two studies contain a shortcoming that seriously affects their interpretability. Survey methodology that relies on self-report as well as questioning patients about hypothetical situations of medication copayments being altered may not report findings that would reflect the actions of that specific population had the copayment actually been implemented.

Summary and Conclusions

There are several mechanisms that government and third party payers can utilize to contain medication costs. There are several American studies that have evaluated the impact of a variety of policies on drug utilization patterns and use of other health care services. Copayment policies have been shown to decrease the utilization of medications in the range of five to ten percent in the American Medicaid population. In addition, the results of a Canadian study examining the impact of a copayment policy on social services clients found that the use of essential drugs decreased and were associated with an increase in serious adverse events and emergency department visits.

Alberta Human Resources and Employment instituted a cost-sharing policy that requires adult clients to pay $2.00 for the first three prescriptions each month. Medications are subject to variable limits on days supply that have been decided upon by health care provider, government and third party payers. A final component of this policy includes the addition of $5.00 to each recipient's monthly support payment to compensate for the possible prescription copayment a client may have to make. The compensation component of this cost-sharing policy makes it unique as no other policies that have been formally evaluated compensate patients for a portion of their prescription expenditures.

Studies examining the impact of cost-sharing policies on hospital admissions, adverse drug reactions and emergency room visits have raised concerns about the detrimental impact to some beneficiaries that occurs when cost-sharing is implemented (Rubin & Mendelson, 1996; Soumerai et al., 1993; Tamblyn et al., 2001). In addition, there is concern that cost-sharing not only decreases the utilization of unnecessary medications, but may also decrease the use of necessary ones. This concern is particularly relevant in populations with high price sensitivity (i.e., the poor) who may forego necessary medications because of their inability to afford them (Rubin & Mendelson, 1996). Therefore, the risk of patients not accessing essential medication poses a variety of ethical issues for policy makers and health care professionals alike.

Another concern lies with idea that drug copayment policies may decrease utilization of not only essential pharmaceuticals, but essential services as well. An example of such a behavior was outlined by Williamson (1998) where individuals in vulnerable populations perceived that they would not be able to afford the prescribed medication and; therefore, did not obtain physician's services. Conversely, a criticism of cost-sharing policy is the possible intentional or non-intentional increase in utilization of other, more expensive health care services. Finally, such policies may create alterations in the behaviors of providers. Waiving of copayments by providers in order to ensure future business from beneficiaries or for charitable reasons is another method by which cost-savings may be minimized (Rubin & Mendelson, 1996).

It is possible that some policy makers do not appreciate the importance of the evaluation of such initiatives nor do they always have the adequate tools to conduct evaluations of such policies. For this reason, it is imperative that evaluations of cost-sharing policies are conducted to allow policy makers to have a framework on which to base future decisions.

CHAPTER 3

METHODS

This study utilized both qualitative and quantitative methods to measure the impact of changes in Alberta Human Resources and Employment (AHRE) drug policy on clients and other stakeholders in Alberta. Several research questions were posed to evaluate the impact of this policy from a number of perspectives. The research questions included:

1) What are AHRE clients' perceptions of the changes in AHRE drug policy, how has it affected them and what other viable alternatives do they perceive to be viable to decrease drug costs in Alberta?
2) How did the changes in AHRE drug policy affect the patients, facilities and services from the perspective of employees of health care and community agencies?
3) How do pharmacists' characteristics relate to their attitudes toward AHRE clients, the policy and its implementation?
4) How has AHRE drug policy affected prescription drug consumption in Alberta?

The study was comprised of three phases. The first phase used focus group methodology to gather information from the various stakeholders that were affected by this policy. The second phase involved the creation and administration of a survey to a random sample of pharmacists in Alberta to examine how the policy was implemented. The final phase of the study involved time series analysis of drug claim data that sought to explain the trends that occurred in drug utilization since the policy's implementation.

Phase 1- Focus groups

Focus group methodology was chosen as the primary means of generating qualitative data to address the response to the policy. The purpose of the focus group methodology in this study was twofold. First, the focus groups generated qualitative data from stakeholders such as AHRE clients, agencies and pharmacists. Second, information from the focus groups served to generate items for the survey of pharmacists that evaluated their attitudes toward AHRE clients, AHRE drug policy and pharmacists' administration of the policy.

A focus group is an interview with a small group of people on a specific topic. This type of interview usually involves five to eight people and lasts approximately one and a half to two hours (Kreuger, 1998; Patton, 1990). Focus group methodology offers several advantages. First, it is a highly efficient technique to gather in-depth information from a number of individuals about a certain topic. Second, because a focus group relies on the dynamics of conversation between individuals, it serves to provide checks and balances that limit extreme views. Finally, focus groups are said to be enjoyable for most participants (Kreuger, 1998; Patton, 1990).

Focus groups were conducted with three groups of individuals including AHRE clients, health care and community agency representatives and pharmacists. These stakeholders were chosen, as it was believed that each would have different, yet pertinent insights into the effects of AHRE drug policy. For instance, AHRE clients shed light on personal experiences of being required to pay the copayment for their prescriptions each month, while pharmacists divulged their experiences in collecting the copayments from the clients. In the following section, a description of the methods of recruitment of each set of participants will be described, followed by the format of data collection and analysis of each of the focus group transcripts.

AHRE client focus groups

Two focus groups were conducted in Calgary and one in Edmonton. Focus group members were recruited through contacts with community agency representatives and the principal researcher. A number of focus group interviews were initially planned as it was believed that AHRE recipients in different cities may experience different financial pressures. For example, the cost of transit and accommodation in Calgary is higher than that of Edmonton. The principal researcher made initial contact with community representatives via phone to explain the purpose of the study and request their assistance in recruiting subjects. Copies of the study information sheet and consent form were sent to these representatives to give them more information about the study and reiterate its purpose. After a pre-determined period of time, the principal researcher contacted the representative again, and arrangements were made for the focus group to be conducted.

Volunteers were considered appropriate to participate in the focus groups if they 1) could speak English fluently, 2) were over eighteen years of age, 3) had experience with Alberta Human Resources and Employment after the copayment and days supply limit policies were implemented and, 4) were willing to share their experiences. AHRE clients were sought that had a variety of medication use experiences to gain an understanding of how the policy may have impacted them. For example, both high prescription drug users (greater than 3 prescriptions per month) and low prescription drug users were asked how the policy impacted them. In addition, AHRE clients with and without dependents and individuals from different AHRE categories (e.g., Assured support, AISH) were encouraged to participate in the focus group discussions to ensure a breadth of experiences were present.

Client focus groups took place in community centres or other locations amenable to the focus group participants. Questions focused on the clients' perceived impact of the policy and addressed both its positive and negative aspects. In addition, the AHRE clients were able to "brainstorm" about possible solutions to rising drug costs. The question guide for AHRE client focus groups is included in Appendix A.

Health care and community agency focus groups

The second set of focus groups occurred in Edmonton with representatives of health care and community agencies. The purpose of this focus group was to understand how representatives of agencies perceived the policy had impacted their agency's functioning and whether they believed it had affected their clients. Because representatives of a variety of agencies were interviewed in the focus group, the impact of AHRE policy change was adequately described in the single focus group interview.

Representatives from agencies were recruited via an initial telephone call from the principal researcher to the agencies. The purpose of the focus groups and how they fit into the larger objectives of the study were explained verbally and agency representatives were asked to participate. Often study information and consent forms were faxed to the agency to ensure that the interested subject had a complete understanding of the study's goals and how the focus group would be carried out. It appeared that some agency representatives presented the possibility of involvement in the study to their supervisors or at staff meetings before they confirmed their attendance for the focus group.

Nominated sampling (Morse & Morse, 1989) was also used to access additional focus group participants. Nominated sampling occurs when a participant already involved in the project assists in the selection of other participants. The underlying assumption is that a research participant would be able to provide an individual who has experience with the subject material and the ability to provide a good interview (Morse & Morse, 1989). For example, if a member of one agency believed that another individual had a different perspective or something valuable to add to the discussion, the inclusion of that individual in the focus group was considered. When nominated sampling occurred, the principal investigator contacted the individual who was recommended and the recruitment process followed the same format as discussed previously.

To meet inclusion criteria for participation in the focus group, representatives must have 1) had personal interactions with AHRE clients, 2) been knowledgeable about the AHRE drug policy changes and 3) been willing to disclose their opinions about AHRE policy, AHRE clients and the policy's impact. In order to foster a candid discussion, subjects who participated were required to be peers within their respective agencies. For example, focus group members from the same agency did not have a reporting relationship with one another. It was believed that an individual whose supervisor was present at the focus group may have been more reticent about voicing his or her opinions on the clients or policy.

The focus group was held in a conference room at the University of Alberta, as this location was central to the majority of agency representatives. The interview asked agency representatives about their experiences with the drug policy, how it may have affected the functioning of the agency and how it may have affected their AHRE clients. The question guide is included in Appendix B.

Pharmacist focus groups

The final set of focus groups was conducted with community pharmacists. Because pharmacists are responsible for collecting the copayment from AHRE clients when medications are purchased, it was particularly important that pharmacists' perceptions about the drug policy were noted. The primary purpose of this focus group was to generate questions suitable for a province-wide survey of pharmacists' attitudes toward AHRE clients, AHRE drug policy and the implementation of the policy in their pharmacies. The second purpose was to explore the pharmacists' experiences of dealing with the policy and their opinions about the policy, qualitatively.

Pharmacists were recruited to participate in the focus groups by personal invitation and nominated sampling (Morse & Morse, 1989). As with the other focus groups, the principal investigator contacted several pharmacies in different areas of the city and outlying areas via phone to ask if pharmacists would be willing to participate. Community pharmacists from a variety of settings were also sought to ensure that a variety of experiences were brought to the focus group interview. For example, pharmacists from independent and chain pharmacies were asked to participate. Study information and informed consent forms were faxed to potential participants. Once they had a chance to review the material, their participation was confirmed via telephone.

Pharmacists were considered eligible to participate in the focus groups if they 1) were practicing community pharmacists, 2) had experience working in community pharmacy (either as pharmacist or intern) both prior to and following AHRE policy implementation and 3) were willing to discuss issues surrounding AHRE clients and drug policy. Pharmacists who were solely employed in pharmacies from affluent areas were not selected for participation, as it was unlikely that they possessed sufficient experience with AHRE clients.

During the pharmacist focus groups, topics that were covered included opinions about the policy, positive and negative experiences with the policy and experiences with implementing the policy in the pharmacy. The pharmacist focus group question guide is included in Appendix C.

Operationalizing focus groups

Each focus group was scheduled to last one and a half to two hours. Initially, the moderator introduced herself and the research assistant. Focus group members had the opportunity to read the study information sheet, ask any questions that they may have had about the study, and then sign the required consent forms prior to the initiation of the discussion. The study information sheets and informed consent forms for the AHRE clients, agency representatives and pharmacists are included in Appendices D, E and F, respectively. A demographic questionnaire was then administered to the group. The demographic questionnaires for the AHRE clients, agency representatives and pharmacists are included Appendices G, H and I, respectively.

Each focus group interview was audio-recorded to ensure that all comments from participants were captured. The research assistant was responsible for assisting the moderator in conducting the interview and taking notes throughout the interview process. At the conclusion of each focus group, the moderator and the research assistant devoted

10 to 15 minutes to a debriefing session that reviewed the proceedings of the group and general impressions of the discussion surrounding pertinent questions (Kreuger, 1998).

Analysis of focus group interviews

Analysis of focus group interviews is an iterative and systematic process (Kreuger, 1998). All audiotapes of focus groups were transcribed verbatim. Research assistant fieldnotes from each focus group were also incorporated into the analysis. Data was analyzed on a line by line basis for each of the transcripts. The first stage of data analysis is open coding. Each idea within the data was given a conceptual label to represent or describe it. Once labeling was complete, the researcher grouped these labels into categories. For example, actions that included arguing about the copayment, trying to "run a tab" and asking for medications free of charge were placed under the category of "avoiding the copayment" (Strauss & Corbin, 1990).

The second stage of data analysis is axial coding. Essentially, the categories resulting from open coding were linked together in various sequences to explore further relationships among them (Strauss & Corbin, 1990). For example, axial coding involved grouping together the categories labeled "avoiding the copayment" and "avoiding the days supply limits" under the more inclusive theme of "policy evasion".

Results from open and axial coding of focus group transcripts are reported in the next chapter of this document. Themes from focus group analysis were also used to complement survey data and place a context on quantitative results. Finally, themes relevant to pharmacy practice and pharmacists' administration of AHRE drug policy were used, in part, to create the pharmacist survey for the second phase of the study.

To ensure rigor in the study, several steps were taken. First, a structured interview guide was used to direct the focus groups in a similar manner. Second, transcription occurred soon after the focus group. Third, the researcher recorded her thoughts in fieldnotes and memos in order to maintain an audit trail which documented decisions made throughout the research process (Sandelowski, 1986). Finally, the principal investigator discussed data analysis with her committee supervisor, who acted as a 'sounding board' for the emerging themes (Kreuger, 1998).

Limitations

There were some limitations in using focus group methodology. First, a focus group interview is limited to a small number of questions to ensure that each participant is able to speak to each topic. A typical focus group interview consists of not more than ten questions. Another limitation is the possibility that a participant may dominate both the conversation and the other participants. For example, in the health care and community agency focus group, one individual dominated the conversation despite several attempts to rectify the problem. An unfortunate consequence of the domination of the topic by one individual may have been that some participants were unable to voice their opinions on certain topics or were hesitant to raise issues that they may have felt were important. Finally, it is always possible that conflicts between group members may arise and status differences in the group may become a factor (Patton, 1990). Mechanisms that included a structured interview guide and the generation of homogenous focus group participants were in place to minimize these limitations (Kreuger, 1998; Patton, 1990).

Phase Two – Pharmacist Survey

A survey for Alberta community pharmacists was developed to understand pharmacists' attitudes toward AHRE clients and the drug policy changes. In addition, how pharmacists administered the AHRE drug plan was explored. Surveys have been shown to be an efficient and accurate method of gaining information from a larger sample of individuals. To make accurate estimates based on a survey sample of individuals, it is necessary to meet four criteria. The four criteria are as follows: 1) the sample is large enough to yield a desired level of precision, 2) the sample is random, 3) questions are asked in a manner that the participants can answer willingly and honestly and, 4) the characteristics of those selected in the sampling process but who choose not to participate have similar characteristics to those who choose to participate (Salant & Dillman, 1994). Information gained for this phase of the study was used to understand how pharmacists administer drug policy and why they may make exceptions to the policy for some clients.

Survey creation

Survey questions were developed, in part, from themes generated in the focus groups. Themes about attitudes toward clients, opinions about the policy and personal stories about policy administration were used to create a pool of possible questions for inclusion in the survey instrument. For example, methods of acquiring copayment from AHRE clients that were discussed in the focus groups were included in the survey instrument. In addition, specific questions of interest to the researchers were also included in the pool of possible questions. For example, a question asking whether it was the pharmacy's policy to waive the $2.00 co-pay for AHRE clients was included in the survey as the primary question of interest. Creating a pool of questions in this manner helps to ensure that the main concepts are fully represented within the survey. By creating a pool of questions in this manner, it was believed that issues would not be inadvertently excluded from the questionnaire.

Survey questions were framed using the methods described by Salant and Dillman to ensure appropriate wording and a good response rate (Salant & Dillman, 1994). Once this had been completed the principal investigator and her supervisor reviewed the pool of questions for possible duplicate or ambiguous questions that were excluded. In addition, questions that did not focus on how the pharmacist dealt with the policy, what the opinions were of the policy or what the pharmacists' opinions were of AHRE clients were excluded. The majority of the questions were assigned 5-point Likert response scales to capture levels of agreement with the statements. Other questions were assigned 5-point rating scales that ranged from never to all of the time to capture the frequency that pharmacists performed certain behaviors. Finally, the question that asked whether it was a store policy to waive the copayment for AHRE clients was assigned response choices of "yes", "no" and "I don't know".

A demographic section was included to gather information about respondent characteristics such as pharmacists' gender, age and years of practice. In addition, pharmacists were asked which type of community pharmacy they spent the majority of their time practicing in and what percentage of the pharmacy's clientele were AHRE clients.

A pilot survey instrument was administered to 20 pharmacists who had experience practicing in the community. The sample of pharmacists included individuals who participated in the pharmacist focus group, graduate students who practice community pharmacy and were not familiar with the project and select pharmacists who had experience dealing with AHRE clients.

Several changes to enhance readability and clarity of questions were made based on the pilot test. For example, an original question that read, "There are only a small percentage of Social Services patients that are abusing the system." was changed to, “There are only a small percentage of Social Services patients that are abusing the Social Services system". Changes to this question were made to ensure that pharmacist respondents would reflect on AHRE clients' use of the Social Services system alone, rather than the health care system or a combination of the two systems.

Subjects in the pilot test also had a few suggestions about the addition of certain questions to both the demographic section and the core instrument. Questions were added to the demographic questionnaire that captured what role the pharmacist held in the pharmacy (i.e., staff pharmacist, manager, owner) and how many hours they spent working in the pharmacy per week. With respect to the core instrument, an additional question that allowed pharmacists to reflect on whether they believed the changes to days supply was appropriate was added.

The survey instrument was then formatted as suggested by Salant & Dillman (Salant & Dillman, 1994). The final survey contained 41 questions with 10 questions addressing how the policy was functioning, 9 questions about how the policy may be affecting clients, 16 questions about the administration of the policy in pharmacies and 6 questions about pharmacists' perceptions of AHRE clients. Each survey was copied onto 11" by 14" paper, folded and saddle-stitched into a booklet format. A cover page and logo was designed to differentiate it from other surveys that may have arrived and to stimulate interest in its contents. A back page with sponsor information and adequate space to place comments was also included (Salant & Dillman, 1994). See Appendix J for the survey instrument.

Survey sample

The sample size calculation was based in part on the primary variable of interest that describes what proportion of pharmacies have decided to waive the copayment policy for their AHRE clients. As there was very little information in the literature regarding the proportion of pharmacies that would waive the copayment, it was estimated that 10% of Alberta pharmacies had made it a policy to do so. Other considerations that were made included the use of multiple comparisons to analyze the data and describe differences between the different types of community pharmacists. The formula used to calculate the sample size was (Lemeshow, Hosmer, Klar, & Lwanga, 1990):

$$n = \frac{(Z_\alpha + 1.26)^2 / \delta^2}{4}$$

If δ is equal to 0.1, a conservative estimate of the incidence of waiving the copayment, then:

$$n = \frac{(2.12 + 1.26)^2}{0.04} = 286 \text{ individuals}$$

Assuming 60% response rate based on previous pharmacist surveys in Alberta, a sample of 500 pharmacists was used (Schapansky & Johnson, 1998).

The Alberta College of Pharmacists provided the random sample of 500 pharmacists. A college representative generated a systematic random sample of community pharmacists residing in Alberta using their Central Information System. In this case, every fourth member was sampled to generate a total sample of 500 pharmacists. The list was then reviewed prior to mailing to ensure no errors or duplicates had been selected. Three pharmacists that participated in the piloting of the survey were excluded from the mailing, as they were familiar with the survey instrument. After the initial mailing had been completed, an additional six individuals were removed from the sample because of incorrect mailing addresses. As well, eight individuals who had been incorrectly categorized as community pharmacists identified themselves to the principal investigator via email, telephone and returned surveys. These individuals were also excluded from the sample. These alterations brought the effective sample size to 483.

Survey administration

The method of administration followed a modified version of the guidelines set out by Salant and Dillman. It has been suggested that high response rates require personalized correspondence, repeated mailings and stamped return envelopes (Salant & Dillman, 1994). For this reason, the intensive, yet previously successful method of conducting mail surveys was chosen.

Initially, all members of the sample received a personalized cover letter about the survey, the questionnaire and a stamped return envelope. The cover letter is included in Appendix K. Approximately one week after the original mailing, a postcard reminder was mailed that thanked all those who had responded and reminded those who had not yet responded to do so. The postcard reminder is included in Appendix L. Finally, a month after the initial mailing, another survey was mailed with a modified cover letter to the entire sample asking those who had not yet responded to respond, a questionnaire and another self addressed, stamped envelope. See Appendix M for the modified cover letter. Because of the sensitive nature of the survey questions and the legal implications associated with the possibility of knowing which pharmacies waived the copayment, it was decided that no identifying numbers or marks would be placed on the surveys to track that they had been received. By providing this additional protection to anonymity of respondents, it was expected that response rate would be maximized (Salant & Dillman, 1994).

Survey analysis

Upon receipt of surveys, the principal investigator entered the survey responses into an SPSS database. Any short-answer comments solicited or unsolicited that were present on the instruments were transcribed for analysis. Once all surveys had been received and entered, a random sample of 30 surveys was selected and each item entry was checked for accurate entry against the original survey. An error rate of 0.03% was calculated, therefore it was determined that it was unnecessary to re-enter all surveys to ensure accuracy.

The responses from the demographic component of the survey were recoded to assist in survey analysis. For example, age was recoded into three categories including 20 to 35 years, 36 to 50 years and greater than 50 years of age. Pharmacy role was changed from three categories to two categories where one category was labeled pharmacy owner/manager and the other was labeled staff pharmacist. Finally, the social services client percentage was recoded into two percentage categories, 0 to 50% and greater than 50%. Descriptive statistics and frequency calculations, as applicable, were performed on demographic data to characterize respondents.

Though items were not grouped into each construct in the survey instruments, an analysis plan was determined. Initially, items were grouped using clinical experience into the subject that they were intended to assess (Juniper, Guyatt, & Jaeschke, 1996).

For example, questions that pertained to pharmacists' compliance with the policy were grouped under one construct. In this manner, all items from the survey instrument were grouped into their respective categories. Items contained within each construct were then refined by examining item reliabilities in each construct. Items with low item-total correlations were removed from each construct in a step-wise fashion as they were deemed detrimental to the reliability of the construct.

Preliminary analysis of survey data involved the examination of differences in construct scores in relation to pharmacist characteristics and practice setting characteristics using analysis of variance (ANOVA). Its use offers advantages over simply using a series of t-tests because it permits the control of alpha at a level determined by the researcher while still providing the ability to compare greater than two means. ANOVA uses an omnibus F-test to determine whether there is any difference among the means. Assumptions of ANOVA include that within each of the groups, the observations are independent and normally distributed and that homogeneity of variance is maintained (Glass & Hopkins, 1996). Finding significant differences using the omnibus F test leads to rejection of the null hypothesis. Where this occurred, Tukey's HSD tests were used to identify where significant differences occurred. This type of post-hoc tests was chosen as it was believed that a more conservative approach that resulted in reducing Type-I errors was preferable over an approach such as the Newman-Keuls method where an increased incidence of Type I error may occur (Glass & Hopkins, 1996).

Further analysis was completed to examine which demographic characteristics contributed significantly to each construct score and to account for possible interactions between these variables. In order to complete this phase of analysis, demographic variables (age, sex), pharmacist title and pharmacy type were included in the ANOVA model along with all possible two-way interactions (e.g., pharmacist title x gender). Two way interaction terms were then excluded in a step-wise fashion in any case were p>0.10. In doing this, the final models contained all main effects and any significant interaction terms.

Written comments provided by respondents on the survey instrument were transcribed. Qualitative comments were analyzed on a line-by-line basis using the technique of open coding to assign labels to each theme present in the text (Strauss & Corbin, 1990). These themes were then categorized into the five constructs present in the survey and used to provide context to the pharmacists' responses in the survey instrument.

Limitations

Survey research has several limitations. First, survey research may be considered obtrusive because it presents an unusual intrusion into respondents' lives and may question them about their values, actions and or beliefs. In addition, because respondents have received a survey asking about a specific topic, their responses may be different than what they would be if they were unaware of what the researcher was interested in (Backstrom & Hursh-Cesar, 1981).

Second, surveys tend to have structured questions that are determined by the researcher. Therefore, the instrument may not capture all of the issues that the subject feels are important. In addition, the researcher runs the risk of introducing issues that are irrelevant to respondents and therefore may be unable to give their opinions accurately.

This issue of irrelevant items was addressed by ensuring that items were generated, in part, from focus group discussions with stakeholders. This ensured that questions would be relevant to the administration and perceptions of the policy. For example, the pharmacist focus group contributed to the majority of the questions associated with the administration of the policy and concerns about pharmacies waiving the copayment for their clients. A further limitation is the fact that the questions were closed-ended (e.g., a 5-point Likert scale) which means that subjects were limited in their choice of responses, therefore the researcher may miss information that the subject would be able to give if the questions allowed for open-ended answers (Backstrom & Hursh-Cesar, 1981). In an effort to alleviate this limitation, respondents were encouraged to include comments about the survey instrument and/or the policy itself in the space provided in the survey. In addition, because it was believed that written comments would provide valuable insight into opinions about the policy and its administration, provisions were made for the analysis of this data. In this manner, it was hoped that any pertinent comments would be present, despite the fact that Likert response scales were used.

The information that is generated from surveys is self-reported. Subjects may answer questions in the manner that they feel is appropriate, rather than answer truthfully in all cases (Backstrom & Hursh-Cesar, 1981). To encourage more truthful responses about the policy and its administration, changes were made to the survey administration suggested by Salant and Dillman (Salant & Dillman, 1994). Identification numbers were not placed on the surveys to assist in tracking which surveys had been received. Though this alteration in the method of administration required considerably more work and expense, it was believed that the subjects experienced a greater sense of security that their anonymity would be maintained. With this greater sense of security, perhaps pharmacists were more likely to answer frankly and honestly.

As well, questions contained personal referents, when applicable, to encourage subjects to respond based on their own experiences and opinions (MacKeigan & Larson, 1989). Two structural features were also used in the survey to prevent acquiescent response set (ARS) from occurring. ARS is defined as a tendency to agree with the statements or questions regardless of their content. To prevent ARS from occurring, negatively and positively worded questions and matched pairs of items were included. Matched pairs of items measure the same opinions but are worded oppositely. For example, one question in the survey was worded, "Pharmacies should have the right to waive the $2.00 fee if they want", while the other question was worded, "There should be penalties for pharmacies that violate the drug plan that requires Social Services patients to pay $2.00" (Ware, 1978).

A final limitation in the survey component of this study was the use clinical experience to categorize the items in each construct. Though categorizing items in this manner avoids grouping of items, which may be counter-intuitive there are limitations with this methodology. For example, items may be grouped intuitively according to the researcher responsible for grouping the questions; however, their clinical experience may be different than other stakeholders viewpoints. A second issue is that this method of grouping items may inadvertently miss a relationship between items that is not immediately apparent without statistical analysis (Juniper et al., 1996). The analysis plan for the survey instrument addresses these limitations by first grouping items then examining their item-total correlations and eliminating the items that do not contribute to the construct's reliability. In this manner, constructs contain items that both fit intuitively and statistically into suitable categories.

Phase three - Time series analysis of drug claim data

To quantify the trends in drug utilization before and after the initiation of the copayment policy for AHRE clients, interrupted time series analysis without a control group was completed. Time series analysis is a useful methodology to assess the impact of a discrete social intervention (McCleary & Hay, 1980). This method is particularly suited to measuring the impact of an intervention on a group of people when a typical control group is not possible (Hulley & Cummings, 1988).

Time series analysis has several assumptions. For example, time series models require that observations be evenly spaced throughout the series. Time series analysis also accounts for dependency that often occurs between repeated measures (McCleary & Hay, 1980). Finally, time series requires that the assumption of stationarity be met. Stationarity refers to the stability of underlying characteristics of the series over time. Specifically, the mean and variance of a series must remain constant over time and stay in a state of equilibrium around a constant level (McCleary & Hay, 1980).

Data from AHRE drug claims were collected from May 1, 1996 to July 1, 1998 for the evaluation of the copayment policy and August 1, 1996 to July 31, 1998 for the evaluation of the copayment policy and days supply limitations. Three main measures of drug utilization were evaluated. The measures included average number of prescriptions per 100 people, average dollars per 100 people and average defined daily doses (ddd) per person.

In an effort to ensure that the sample demographics were homogenous at each time period, only drug claims from long-term user categories were accessed. These long-term user categories included AHRE client sub-categories 32, 33 (Transitional support), 42 (Assured support) and sub-category 91 (Straight AISH). Due to limitations in the data provided, patients' movements in and out of the social services programs (e.g., due to death or changing financial situations) could not be captured. Further, demographic information (e.g., age, sex) was captured for only those patients with claims for the specific medications examined within the study period.

Initially, number of prescriptions per patient per month and cost of prescriptions per patient per month were calculated throughout the defined time period. Defined daily dose per person (ddd) was calculated at monthly intervals to assist in quantifying the effect of AHRE changes. Defined daily doses (1999) were calculated for each claim by multiplying the quantity of the drug in each prescription by the strength of the preparation for each prescription, summing all the prescriptions per person, then dividing this sum by the assumed dose per day for the drug used in its main indication for adults. This provided a variable of ddd per person per month. The advantage of this method is that it is possible to aggregate different agents within one therapeutic class for analysis (Maxwell, Heaney, Howie, & Noble, 1993).

Select drug classes were used to evaluate the effects of each policy. One set of analyses assessed the effects of the $2.00 copayment on three therapeutic categories, the other analyses assessed the effects of both the $2.00 copayment and days supply limits on three other therapeutic categories. The therapeutic categories are designated by the AHFS Pharmacologic-Therapeutic Classification system outlined by the American

Hospital Formulary Service (McEvoy, 1996). Therapeutic classification is a widely used means of organizing medications in groups with similar activities and uses. These classifications are designated in a numerical manner. For example, 28:08.04 is the AHFS Pharmacologic-Therapeutic Classification for salicylates.

For the purposes of accessing the data, a list of medications in the therapeutic classes of interest was generated, along with the medications' current DINs. This list was submitted to Alberta Blue Cross as part of the data request. Any potential changes to DINs during the study period were noted by ensuring that the previously used DINs were linked with those contained within the data request. Any claims submitted and then subsequently reversed were removed from the data set.

Policy One - $2.00 copayment

For the purpose of evaluating the effect of the copayment on drug utilization, medications with 100-day supply limits were collected. Three therapeutic categories were selected to reflect medications used on a continuous basis to treat chronic conditions. One sub-category of cardiovascular drugs and two sub-categories of anti-hyperglycemic agents were examined. Specifically, angiotensin-converting enzyme (ACE) inhibitors (24:04) and anti-diabeticagents, sulfonylureas (68:20:20) and miscellaneous anti-diabeticagents (68:20:92) were analyzed. These classes of medications were chosen because they were considered essential medications used to treat chronic conditions of hypertension and diabetes, respectively (Dipiro et al., 1997). In addition, other researchers have expressed concern that the utilization of essential medications such as these may decrease when patients are affected by cost-sharing policies (Reeder & Nelson, 1985).

Nine models were created to analyze the impact of the \$2.00 copayment. The impact of the policy on each of the three therapeutic categories was reported as average number of prescriptions per100 recipients per month, average dollars per 100 recipients per month and average ddd per recipient per month. A transfer function ARIMA model for time series data was used to describe the policy's effects. We assumed that the intervention (policy) would have a long-term effect on drug utilization, therefore a step function for the intervention was used:

$$Y_t = \{W(B)/D(B)\}X_t + N_t$$

with

$$N_t = \{M(B)/E(B)\}e_t$$

Where W(B) and D(B) are the numerator and denominator for the intervention series X_t respectively, and $X_t = 1$ for months following November 1997 and 0 otherwise for all of the drug claims data. N_t is the noise component of the model where M(B) is the numerator for the noise series, E(B) is the denominator and e_t is white noise, The W(B), D(B) and the ARIMA models for N_t were chosen to produce the response that was expected by the policy change for each therapeutic category. If the existence of trend or seasonality was present upon graphical examination of the data, a more general model that included these additional components was used.

Policy Two - \$2.00 copayment and 30 days supply

The combined effect of 30 days supply limitation and co-pay implementation, was evaluated using three therapeutic categories of central nervous system agents. The first category of medications was therapeutic category 28:28:00, anti-manic agents that consisted of lithium alone. The second category was anti-depressants or 28:16:04.

Because this category is broad and encompasses a variety of anti-depressants, we elected to use data from prescriptions of selective serotonin re-uptake inhibitors (SSRI's). The final category that was examined was anti-psychotics. For the purpose of this study, clozapine, a medication within category 28:16:08 was excluded, as patients receive a limited days supply because of additional monitoring that is required to prevent adverse effects of this drug (Gillis, 2000).

Nine models were created to analyze the impact of the \$2.00 co-pay and 30 days supply. The impact of the policy on each of the three therapeutic categories was reported as average number of prescriptions/100 people and average dollars/100 people and ddd/person. A transfer function ARIMA model for time series data was used to describe the both policies' effects.

Because the policies were expected to have a lasting effect, a step function was used:

$$Y_t = \{W_1(B)/D_1(B)\}X_{t1} + \{W_2(B)/D_2(B)\}X_{t2} + N_t$$

with

$$N_t = \{M(B)/E(B)\}e_t$$

Where $W_1(B)$ and $D_1(B)$ are the numerator and denominator for the intervention series X_{t1} respectively, and $X_t = 1$ for months following November 1997 and 0 otherwise. $W_2(B)$ and $D_2(B)$ are the numerator and denominator for the intervention series X_{t2} respectively, and $X_{t2} = 1$ for months following January 1998 (0 otherwise) for the utilization of each of the therapeutic categories selected. N_t is the noise component of the model where M(B) is the numerator for the noise series, E(B) is the denominator and e_t is white noise. The $W_1(B)_1$, D(B), $W_2(B)$, $D_2(B)$ and the ARIMA models for N_t was chosen to produce the response expected by the policy change for each therapeutic category. Again, if trend and seasonality was confirmed a more general model that included these two components was described.

The model building process

The process of model building used in this study was originally outlined by Box and Jenkins in 1976 and involves the processes of identification, estimation and diagnosis (McCleary & Hay, 1980; Jensen, 1989). Appendix N provides detail on the model building process and sample output.

Limitations

There are limitations associated with time series methodology. The results of time series analysis may not be valid if an event occurring simultaneously with the intervention causes a change in utilization. In addition, a change in utilization due to impeding policy changes or past events not accounted for in the series may negatively impact the results. These threats to validity may be alleviated by the presence of a control or comparison group (McCleary & Hay, 1980). In fact, the lack of a comparison group has been criticized as a weakness that does not allow unequivocal evidence that drug policy changes have affected drug utilization (Soumerai, Ross-Degnan, Fortess, & Abelson, 1993). However, because a comparison group was not feasible in this study, other measures were taken to assist in the description of the impact of drug policy changes. For example, triangulation of the results of the time series analysis with survey and focus group data provided context for changes in drug utilization.

Ethical Considerations

The Health Research and Ethics Board (Panel B) at the University of Alberta granted ethical approval for this study. Consent of the participants was obtained prior to the initiation of the focus group interviews. At that time, it was explained to the participants that they were not obligated to answer each question and that they may withdraw from the focus group discussion at any time without penalty. Confidentiality was maintained by removing all identifying characteristics from the transcripts. All information from phase one of the study, including demographic questionnaires, transcripts, fieldnotes and audio-recordings will be kept in a locked cabinet for a period of seven years as specified by University of Alberta regulations. Only the principal investigator and her supervisor have access to this cabinet.

The Alberta College of Pharmacists provided a random sample of practicing Alberta community pharmacists. That list was destroyed at the completion of the final mailing to protect the identities of survey respondents. In addition, due to the sensitive nature of the survey, the research team decided not to use identifying markings on the survey to track the receipt of survey instruments. It was decided that the possibility of the research team knowing which pharmacies waived the copayment could have ethical implications. For that reason, two mailings of the survey instrument were made to potential respondents. Completed survey instruments will be kept in a locked cabinet that only the principal investigator and her supervisor have access to.

AHRE drug claim data was requested from Alberta Blue Cross for the completion of the time series analysis. In order to protect the identities of the claimants, patients were reported in an anonymous and unique manner and ages were reported by birth year and calculated subsequent to receiving the data. Data were kept in a locked cabinet that only the research team had access to.

CHAPTER 4

FINDINGS

The policy analysis of the Alberta Human Resources and Employment drug program changes had three phases that addressed the research questions comprising the process and impact evaluation. The first phase of the project involved focus groups with AHRE clients, health care and community agency representatives and pharmacists. The second phase involved the creation of a survey that was administered to a random sample of Alberta pharmacists. The survey was intended to measure their attitudes toward the policy and social services clients as well as determine their compliance with the policy. Finally, time series analysis of drug claim data was completed to evaluate the impact that the policies may have on social services clients' use of medications as well as costs incurred by Alberta Human Resources and Employment. The following chapter will review the results of each of the phases of the study.

Phase 1 - Focus group interviews

Alberta Human Resources and Employment Client Focus Groups

Three focus groups were held with individuals who had received or were currently receiving assistance from Alberta Human Resources and Employment to gain insight into their experiences with the drug policy changes. Two of the focus groups were held in Calgary and one focus group was held in Edmonton. The majority of the comments delved into the process of policy implementation, as clients had the most experience with this area. However, some comments about possible impacts of the policy and suggestions for its improvement were made. The following section will first review clients' opinions about the policy and social services, then discuss their personal experiences. A brief overview of what they perceived to be the impact of the policy and finally, their suggestions for changing the policy will be discussed. The three focus groups have been presented in an aggregate manner as each group discussed similar themes during the focus group interviews.

The sample

Descriptive data was available for two of the three focus groups. The first focus group contained seven individuals who were all female. Their mean age was 29.57 years (± 6.88 years) with their ages ranging between 22 and 43 years. The majority of the women interviewed were single (n=4), one was widowed and two divorced. Participants cared for between one and four children. The participants also had range of time on social assistance extending from one to 108 months with a mean time of 36.4 months (± 46.8). Finally, each individual respondent received a mean of 2.21 prescriptions per month (± 1.04).

The second focus group had ten participants who ranged in age from 21 to 59 years (mean 29.22 ± 12.64). Each of the participants was female. Two were married, six were single and two divorced. All but one of the women interviewed had children. Women had a range of one to three children that were currently under their care. The time that the participants had spent on social services ranged from two to 96 months with a mean time of 44.89 months (± 33.0). As well, individuals had a range of experiences with obtaining prescriptions as they received between one and six prescriptions per month (mean 2.71 ± 1.89)

It was not deemed possible or appropriate to gather demographic information from the third focus group for several reasons. First, the focus group was held in an inner city drop-in centre with individuals who were wary of government and other "authority". Second, they were concerned that participation in this interview would come with the possibility of retribution (e.g, losing their social assistance). These concerns were evidenced by the lack of participation in the interview despite the large pool of individuals who were approached. The centre's representative advertised the focus group in the centre for approximately two weeks prior to it occurring. Approximately one hundred people were in the drop-in centre at the time that the focus group was announced. Of these individuals, six expressed an interest in participating in the focus group. Of the six who were originally willing to participate, one individual declined to be interviewed because it was being audio-recorded and he was required to sign a consent form. Finally, when first approached about the possibility of holding a focus group interview in the centre, the agency representative expressed concern about the documentation that participants were required to complete prior to participating in the interview. First, she was concerned that her clients would not be willing to sign a consent form. Of those who may be willing to do so, she believed that they would be intimidated by its format and would have preferred to sign a simple sentence that said something similar to "I agree to participate". She expressed that illiteracy and their distrust of formal procedures such as the consent form would be a major deterrent to the completion of a focus group in her agency.

Despite these obvious limitations, it was believed that this clientele, comprised of transient and marginalized individuals, would have different and insightful comments to make that would contribute to the understanding of the impact of the drug policy. In order to ensure maximum participation in the interview, it was decided that the participants would not be required to complete the demographic questionnaire, however they would be required to complete the consent form. Again, because of the unique clientele, the agency representative had suggested that she remain present during the discussion to ensure that her clients were comfortable. The agency representative completed an informed consent form as a component of her participation. Her inclusion in the focus group process was not determined to be a hindrance as she simply clarified comments made by individuals in the interview, when required. Clarification of comments was necessary in cases where, for example, the participants used terminology that was not familiar to the researchers. The agency representative did not interfere with participants in the focus group, nor explicitly temper or change their responses. In [illegible], her participation in the focus group provided credibility to the research initiative in the eyes of the participants and she assisted in maintaining order during the interview. The participants of this Edmonton focus group were all male and appeared to range in age from early twenties to mid-fifties. During the focus group, some reflected that they had been on social services for a short time or intermittently while one gentleman indicated that he had used social assistance for a longer period of time.

AHRE clients' opinions

Perception of AHRE. The majority of the comments that were made about Alberta Human Resources and Employment suggested a negative view of the program and a general concern that clients were given too little money to survive. These perceptions became evident when the clients spoke about the policy and the difficulty in affording the copayment. For example, one woman said:

> *The amount they give you for a teenage boy on welfare is eighty-five bucks a month for food. I'm just saying that if you're having to have medication, you shouldn't have to pay for it. Period.*

Another added to the point when she said simply:

> *Two dollars is a lot of money on what social services gives you.*

Similar concerns were reiterated by almost all of those interviewed. One focus group participant, however, did offer her appreciation of the system when she said:

> *You know what? I have been taking medications for 15 years and I have only used social services twice. I know I am living with it right now and I'm appreciative of just paying the two dollars. They help me when I can't help myself. I really don't mind paying the two dollars. You know what I mean.*

The policy. During the focus group interviews, participants expressed several of their opinions about the policy in general. Most thought that the policy was nonsensical, as they believed it was futile to give people five dollars and then take away six dollars if they filled three prescriptions. One participant said:

> *Yeah, but it is ridiculous. They want you to pay two dollars and they give you five dollars to cover it. Why don't they just say, forget the two dollars and not give you the five.*

Often these comments were linked to the belief that individuals did not have enough money from AHRE in the first place, therefore the copayment was a hardship for them.

> *Why give only five dollars and not six dollars? Where do we get the dollar? We are poor. Rent is $228 and we get $212. So you get extra money from food.*

AHRE clients' Process evaluations

Lack of dissemination. One of the main concerns that emerged from the focus groups was that AHRE clients did not feel they were adequately informed about the policy. More than half of those interviewed believed that the policy changes were not advertised to them. Some of the individuals commented that they remembered the notice of the change in policy attached to their monthly cheque, but believed that it was not sufficient for all of the clients to be appropriately informed. For example, one woman said that the policy change was noted by a small "blurb" on the cheque.

> *Advertised on cheque stub. On bottom notes. Was only one line: $2.00/prescription.*

Comments were also made that even though the change in policy may have been listed in documentation sent to clients, AHRE had failed to recognize that a portion of their recipients were illiterate.

Clients recognized that pharmacists were often the individuals who conveyed the policy to them when the change occurred. Overall, they felt bad for the pharmacists and believed that they should not have had to inform AHRE clients. One participant said:

> *Pharmacists had to take the brunt of it. Social services should take responsibility for it [advertising the policy] and not get others to do it.*

The timing of the advertisement of the policy as well as the policy change was also criticized in these interviews. One individual believed that the policy could have been announced well in advance of its initiation. The agency representative present at the Edmonton focus group noted that the policy had emerged at approximately the same time as the requirement for AHRE clients to have bank accounts for direct crediting of monthly support cheques. In her opinion, the prospect of having to set up a bank account was so daunting for her clientele that the news of the two dollar copayment for prescriptions was overshadowed.

The lack of knowledge about the policy as well as the time of its implementation created some uncomfortable situations for clients. More than half of those interviewed had an embarassing story or anecdote that occurred in a pharmacy because of their lack of knowledge of the policy.

> *I didn't have the two dollars because I didn't know. She [the pharmacist] said, "Well, if you don't have the two dollars then you're not going to get the*

> *prescription." OK. So I had to go all the way home. Scrape up the money and come all the way back.*

Another participant illustrated the embarrassment that occurred in the pharmacy when clients were unaware of the policy when she said:

> *Well, because I wasn't aware of the changes in the policy when I was receiving assistance. So I went in to get prescriptions which I already got. And I had no rapport with them at all.... went in, didn't have the two dollars and was basically chastised and humiliated in front of other people. It was gross.*

Charging the co-pay. There was a great deal of discussion about which pharmacies would waive the copayment on the clients' behalf. One participant made an educated guess about the prevalence of pharmacies waiving the co-pay when she said:

> *I think it depends on where you go to. I'd say that about 70% on average will say that they will let it [the co-pay] go. But some will want the money. They'll say, "I'm sorry but we can't give you the drugs."*

According to the AHRE clients, pharmacists manage the policy in a variety of ways. First, there were pharmacies that strictly followed AHRE policy and charged the co-pay for everyone. For example:

> *Some pharmacists won't give it to you if you are a quarter short.*

Another client said that pharmacies would even charge you if you needed medication to treat a chronic illness:

> *I'm a diabetic and I didn't get it because I didn't have the two dollars to pay for it.*

The second way of dealing with the policy appeared to be pharmacies that made it a "policy" to waive the fee. One participant said:

> *My pharmacy never charges me and I have been going back for four years.*

The third method of dealing with the policy was to be inconsistent in charging the fee. This type of behavior appeared to be mainly pharmacist-specific rather than a directive from the store. Clients said:

> *And then another time, they said just don't worry about it. That was a woman who really worked there. But she was really wonderful about it.*

A similar comment was:

> *It depends what you get. I know a pharmacist who'll be more flexible in giving it to me.*

The fourth method was to give a client a small supply of the medications and ask him or her to return with the copayment for the remainder of the therapy. This appeared to allow pharmacists to provide necessary care to their clients while still ensuring that they charged the two dollar copayment. An example of this method was cited when a participant said:

> *So they gave me a couple and then I came back by the time the cheque came in.*

The final method that pharmacists used was to allow clients to "run a tab" for their medications.

> *Had the fee waived. They say, "I'll trust you. You'll come back when you have the two dollars."*

In these types of cases, it was difficult to tell whether the pharmacists would actually collect the copayment or if they were really avoiding the policy. Comments from some of the clients indicated that they would never return to pay the pharmacy what they had owed or that they were sure that the pharmacy would never collect the copayment.

Interestingly, these questions about the stores collecting the copayment often sparked a great deal of "side discussions" during and after the focus groups about which pharmacies would waive the fee or "run tabs" for clients. The Edmonton focus group added somewhat to this discussion when a client said that there were certain types of stores that he avoids because of the possibility that they would charge the fee. For example, he said that he would only go to smaller stores and not the large chain stores because the larger ones were less likely to waive the fee or allow him to have a "store credit".

AHRE clients' impact evaluation

Clients also had insight into the possible impact the policy may be having on the AHRE community. A concern voiced by clients was the fact that some people would delay seeing their physician until they could afford the prescription that the doctor would likely write for them. This indicated that clients believed that there may be some delays in seeking care due to the copayment. Another concern emerged that patients may be taking non-essential medications and avoiding essential ones in an effort to save money. One participant mentioned that people would still pay the two dollars but would avoid paying for something that they might need if they couldn't "feel" it. Others suggested that two dollars may not seem like a lot of money to many individuals, but when a person is living on a limited income, the two dollars could be used for a variety of necessary items. For example, one participant said that many times she has avoided filling her own prescription because the two dollars that she would have spent in the pharmacy could buy two litres of milk for her child.

Finally, some clients may share their medications and their copayments in an effort to save costs. An example was given about the sharing of antibiotics where one client would fill a prescription, pay the two dollars, then have another client pay one dollar for half of the prescription. That way they believed that they were being treated for the same thing and sharing the cost of the copayment.

Despite the fact that clients believed that the policy may be harming people who needed medications, they said they believed the policy had done little to curtail the abuse of the system. One individual said that he "didn't see any decline in people getting high" and another commented that two dollars still remained a relatively inexpensive "high" for abusers. As well, if an individual was selling prescription medications on the street, they were essentially being reimbursed several times over for their copayment.

AHRE clients' suggestions for change

One focus group had two specific suggestions for controlling drug costs of the AHRE program as well as abuse without harming individuals who are not abusing the system. The first suggestion was to initiate random investigations of people's medical profiles to see what type of medications a client receives and the frequency with which he or she receives it. One client said:

> *Could do random investigations on what you are getting. Check out why you are getting sick.*

A second suggestion was to just have people disclose the type of medications that they needed to be on to AHRE. In this way, it was believed that AHRE could investigate clients who were not taking medications that were used to treat any conditions they may have. There seemed to be little concern that either of these suggestions may infringe on a client's privacy.

Summary

In summary, AHRE clients believed that social assistance was a useful program of last resort, but the copayment remained a hardship to clients because of the fiscal restraints imposed on them. Focus group participants also felt that the policy did not make sense and the thought of charging for prescriptions and then partially compensating for them seemed a pointless exercise. Clients felt that there could have been improvements in the dissemination of the policy. In addition, they noted that pharmacies implemented the policy in a variety of ways. Finally, participants suggested that the policy may be causing some people to neglect their health or take medications selectively in order to save money.

Agency Representative Focus Group

Analysis of the focus group with agency representatives resulted in comments about the process of policy implementation in the community and the impact of the policy on the various stakeholders. Initially, participants of the focus group interview and their opinions about the policy will be described. The participants' opinions of the policy's implementation will be reviewed and, finally, their beliefs about the impact of the policy will be described. Overall, the policy changes were not well received by the agency representatives who were concerned about the possible hardships that their clients may have suffered because of the policy.

The sample

Nine females participated in this focus group. The participants' professional backgrounds were predominantly nursing (n=4). The remainder had backgrounds that included education, arts, community work and social work. There was a broad range of experiences presented, evidenced by the fact that the agency representatives had worked for their respective agencies for periods ranging from 1 year to almost 30 years. The mean time that they had spent working in the community was 7.78 years (± 9.25 years). Finally, when asked what percentage of time they spent working with AHRE clients, the mean time was 27.74% with a range between 20 and 100%.

Agency opinions about the policy

Generalizations about the poor. Opinions of the AHRE policy changes were generally negative. Representatives supported their opinions of the policy with several statements about their experiences. The participants did not approve of the policy because they believed AHRE clients already bore the brunt of many cost-sharing initiatives that the government had put in place. One representative suggested that AHRE clients were being singled out because of increasing drug costs:

> *Well, the drug prices are going up for all populations. For seniors, for the disabled, for all populations. Why does the poor, why are the poor singled out as the bad example of drug costs?*

Another participant echoed this comment when she spoke of the policy changes in place for specific populations, such as the disabled. She believed that many unfair generalizations had been placed on AHRE clientele.

> *I think that as far as Social Services insults go, this one is fairly minor. But for them to presume that people on welfare abuse their medications, I think that is a terrible premise and I think they have a lot of nerve going on television and saying, "Oh, people with disabilities are abusing their medication."*

Vulnerable populations. Agency workers were particularly concerned that AHRE clients would be negatively affected by the policy because they were vulnerable to cost increases due to their limited incomes. Often this population did not have the capacity or "safety net" that other populations may have to help deal with the hardship. One woman focused specifically on her AISH clientele when she said:

> *And I am particularly concerned with people with disabilities and although we only end up paying a dollar there's 23 000 people with disabilities....that's 23 000 dollars a month that they are clawing back from people with disabilities.*

Another participant added to this statement when she reflected on the specific population that she dealt with. Her clients appeared to be especially vulnerable to policy changes for prescription medications as they were not functioning at the level of the average AHRE client.

> *I'm talking about inner city clientele that I work with, with the majority of them to have a bad addiction problem, or a diagnosis with mental health. So I am dealing with a particular type of person. To me, this has hurt them terribly... They can't manage very little hygiene let alone money matters.*

Teaching responsibility. Another theme that emerged from the discussion was the belief that AHRE implemented the policy as a means of teaching individuals responsibility for budgeting and medical care. This was insulting to the representatives, as they believed that their clientele were particularly vulnerable individuals. One participant stated:

> *I mean it seems to me the whole thing about giving the five dollars and then taking it back, it's some sort of distorted way of thinking that they are going to teach somebody responsibility when it's not even about that. It's about survival.*

Lack of understanding. Many of the agency representatives were disappointed with the lack of support or advocacy given by health care professionals and their respective organizations. The participants suggested that pharmacists and physicians, and their respective organizations had done little to try to stop the policy's implementation. They wondered aloud why health care professionals were not as sympathetic as they could be toward AHRE clients.

> *I think they [health care professionals] need education in regard to real life and it's not just about writing a prescription and handing it over. They have to ask more questions or get to know their client. "How are they going to get home?" These are some of the things we live with every day. Each and every one of us and now we think this way. But it's surprising the number of people who leave the hospital and walk home with a freshly put on cast and crutches to find accommodations which they didn't have when they left the hospital. So, it's just I don't think it's people not being concerned, I think they just don't think in this way.*

This comment was reiterated when a suggestion was made on how to rectify the problem. One woman stated:

> *I'm saying a lot of people don't think in this way and I feel every physician and every social worker should in fact work for a period of time in the inner city to realize that not everyone has what everybody else has or the means to get it, or the family support that was needed. It's just a new way of thinking that we have to educate and even pharmacists too. I think every profession that has a business or any kind of dealings with that underprivileged area or group should know something about these types of things so that they can help in some way. Instead of making people think they have deserted you.*

Just the beginning. Finally, one of the greatest concerns was that the copayment may be just the beginning of increasing cost sharing measures that would negatively impact social services clients. One representative said:

> *It's really the idea of it's two dollars now what happens when it's ten? And it becomes more and more, and the pharmacies can't waive it and we can't come up with it in out little trust fund that we have in the bottom drawer or that we have in our own pocket because we know what's going on. So the worry is much more when it goes up.*

Agency representatives' process evaluation

Lack of dissemination. Representatives felt that the average AHRE client may not have understood the intricacies of the policy. Participants suggested that they spent an inordinate amount of time explaining the policy to the clients during its introduction. There was concern that the clients understood the fact they would be required to pay $2 for their prescriptions, yet they did not understand that they were compensated with $5 a month. For example, one representative said:

> *They don't even know that the extra five dollars is for the prescription.*

Charging the copay. Agency representatives were cognizant that a $2 copayment for medications was waived in some pharmacies. Agency representatives tended to believe that waiving the fee was admirable. Representatives believed that pharmacists were waiving the fee for the good of their clients as well as their businesses. One participant said:

> *Our pharmacy will forsake the prescription fee and in particularly because we get our prescription through one particular pharmacy and so therefore we're creating a business for them as well.*

Though many of the participants knew that select pharmacies were waiving the fee, they suggested that it was difficult for both clients and agencies to predict which pharmacy would waive it for them. One respondent said:

> *The pharmacies that only charge a very small amount for prescription fees like the big Superstores and things like that, I don't know if they would forsake those two dollars. But the others that are more convenient to the client the little pharmacies that are close in where they can be accessed, generally charge the very high prescription fee. And the majority of them will not relinquish the two dollars. So there are some that will and some that won't.*

Agency representatives were also privy to knowing which individuals also assisted AHRE clients in avoiding the copayment. One participant said that she knew of other health care professionals who had assisted their clients when they were unable to purchase a prescription.

> *Another comment from a physician was that the staff end up giving clients the two dollars they need to pay for the costs. Most of the patients on social services have very little money and the two dollar fee can be prohibitive.*

Interestingly, some agency representatives were required to collect the copayment if their agency dispensed medications to clients on behalf of a pharmacy.

> *I become a collection agency for the pharmacy. We have five pharmacies delivering to our clinic, methadone doses for fifty people. So everyday we get a delivery from five pharmacies and attached will be notes. "So and so owes us two dollars for the month."*

In addition to the act of collecting copayments being draining on the agency's staff, this responsibility may have had unforeseen consequences on clients' relationships with agencies. One agency representative suggested that there were negative repercussions:

> *And here we are being the collectors and what happens if we can't collect and we're hassling them? And it sets up a whole dynamic of not trusting you, because you are hassling them for money now. And you know the pharmacist, you want to have a good relationship with them and it's a whole dynamic that was never intended to be happening for people who are interacting in those people's lives in different ways.*

Days supply limits. The participants believed that a positive aspect of the policy was the days supply limitations. Each of the representatives felt that these limits assisted patients in maintaining compliance and helped to prevent any abuse of medications. One respondent stated:

> *Their ability to look after themselves in an independent setting is not great with my clientele and it always amazes me when someone came out with a three month supply. I'm in favor of the repeat prescriptions and the thirty-day thing...I think they should have a little more supervision in regards to the amount of medication they get. And also for our addiction patients.*

Another representative agreed with that point when she said:

> *Yeah, most of my contact is with mental patients and nearly all of them get thirty day supplies. And I agree with you. A thirty day supply is good to check in with your doctor once a month. I don't think it's too much to ask.*

Agency representatives' impact evaluation

The agency representatives that participated in the focus group interview also had concerns about the impact of the policy on their clients. Agency representatives believed that clients were choosing to fill non-essential medications rather than those deemed essential. One woman said:

> *You will find that if they have a prescription, say with antibiotics and analgesics and Tylenol #3, they will have scrounged up two dollars to take the Tylenol #3 but leave the antibiotics.*

The issue of greater expenditures in other sectors was a concern for more than half of the representatives who participated. They feared that the choices clients may be making would be the cause of greater health care expenditures in other sectors. For example, patients may turn to the hospital for care because of non-compliance with prescribed regimens. One representative illustrated this point when she said:

> *Most patients on social services have very little money and the two dollar fee can be expensive and so most end up doing without important medication due to this. And I think that's... I would concur with what [another participant] was saying, so they don't get the antibiotic and they end up in Emerg a few days later with a terrible infection that requires IV drugs.*

The shifting of pressures from AHRE to the agencies themselves was of great concern to the participants. They perceived that their respective agencies had also borne the brunt of the policy. Often agencies and their employees felt obligated to find a resolution that would allow clients to access the medications they needed.

> *Particularly for our clients, where a lot of other people would just buy certain things for hemorrhoids or you know, we'd just buy it and give it out to people who can't afford to get it. But you know, I think there's... even at a birth control clinic, I mean, we go through an inordinate amount of work to try and figure out for people what's the easiest and the best way for them to get what they need.*

Despite each of the agency's concerns about clients' health and finances since the policy's inception, the representatives believed that the policy itself was futile, if it had originally been intended to help control costs. One representative said:

> *But I find that whoever thought this was any partnership in responsibility, the administration costs of administering this in the first place was...out weighed the cost that they saved or which it enforced the client to go to the emergency department. And that's creating more costs for the government in the long run and that's poorer service for the clientele. And if this is the case, the simplest way would be to take a dollar off the their cheque rather than five dollars on their*

> *cheque if they want to teach them anything at all. So to me, it's not only hurt the clientele but it's created more pressure on the other health care services, as in ourselves and the hospitals, by creating... They're getting sick by not taking their medications or they don't have their two dollars, so they will go to where they can get it free, which costs another doctor's visit. So we're defeating the whole purpose. That's my opinion of it.*

Finally, some of the representatives expressed concerns about the health care professional left with implementing the policy – the pharmacist. Between pharmacies competing for business by waiving the fee and the increased amount of work that they felt pharmacists had acquired with the policy's implementation, they feared for the viability of some of the inner city pharmacies.

> *They're an incredibly good pharmacist and they do way more than most pharmacists do. And they are really taking the brunt of it and I feel for their business and worry about it because, you know the inner city is small and when you're a small, private business, you don't have the backing of someone like London Drugs or Safeways.*

Summary

The results of the focus group suggest that agency representatives were frustrated with both the process of policy implementation as well as its possible negative consequences. They believed that the clients they worked with had been singled out to bear the consequences of cost control measures implemented by the government. They also thought that this hardship was compounded by the fact that they were vulnerable and possessed the least resources and support. In general, agency representatives believed it was admirable for pharmacists to waive the fee. They also expressed concerns that they had been required to collect copayments on behalf of some pharmacies and that this may have negatively impacted their client-agency relationships. They were also concerned that this policy may be only the beginning of further and more decisive cost containment measures. Agency representatives believed that AHRE clients may be filling non-essential medications rather than those for chronic conditions. Finally, they believed that the policy may be having a "trickle down" effect where other agencies, pharmacies and institutions were being forced to compensate for the problems caused by the policy.

Pharmacist Focus Group

The focus group interview with community pharmacists from Edmonton and surrounding areas produced descriptions of opinions about the policy and its methods of implementation and impact. The majority of the comments about the policy were focused on the process of policy implementation, as pharmacists had the most experience in this area. The pharmacists reflected on what they believed the impact of the policy was on drug utilization, drug abuse and their patients' lives. The following sections will first review pharmacists' opinions about the motivation behind the policy's implementation and will then discuss their experiences with the implementation of the policy in community pharmacies. Finally, a brief review of their opinions about the impact of the policy will be presented.

Sample

Nine pharmacists participated in the focus group interview. Five of the participants were female. The subjects had practiced pharmacy between one and thirty years with a mean time of 10.1 years (± 9.8 years). There was an almost even division among the different types of pharmacies present, with chain, grocery and retail pharmacists comprising 55.5% of the group and independents 44.1%. A range of 20% to 45% of their pharmacies' clientele were AHRE clients.

Pharmacists' policy opinions

Reasons for implementation. Initially, the pharmacists discussed what they believed to be the philosophy supporting the policy's implementation. Pharmacists believed that one of the main reasons for the policy's creation was to teach fiscal responsibility to AHRE clients. For example:

> *A little bit more responsibility. They're learning that they may have to put forward the two dollars and so any of the month anyway they are thinking, "OK. So I know I may need these medications, so I have to keep the money aside."*

The second reason pharmacists cited for the policy's implementation was to curtail abusers of prescription medications. Each of the pharmacists had anecdotal experiences with AHRE clients who were abusing the system by methods that included, for example, seeing more than one physician for the same problem and obtaining unusually large amounts of medications.

Opinions about the policy. Pharmacists possessed several opinions about the AHRE cost-sharing policy. Overall, pharmacists resented the copayment portion of the policy, as they tended to be the enforcers of the policy. This combined with the fact that all of the pharmacists participating in the interview were confused about why clients received a copay allowance of five dollars on each cheque, made them resent the policy even more. Two of the nine pharmacists interviewed went so far as to say that they perceived the cost-sharing policy and copay allowance to be a bribe for AHRE clients. One pharmacist stated:

> *I think for some of them, the two dollar co-pay, or the five dollars they get every month, the way they look at it, it's like a bribe not to get prescriptions. .....Now they have to ....you have that five dollars for some of them, they count every penny, and that extra five dollars a month, for some of them is an incentive to say, "Well, do I really need this prescription? I could use the five dollars a lot more."*

Despite pharmacists concerns and negative views of some of the policy's components, all of the members of the group believed the days supply limits were reasonable and beneficial. For example, the pharmacists stated that thirty days supply limits on certain medications assisted pharmacists in monitoring patient compliance. They also believed that limiting prescription medications to a one month supply may save AHRE money over the long term as they believed that there was a great deal of transience in the social services system. Finally, pharmacists conceded that decreasing days supply limits was financially beneficial for the pharmacies because patients were required to fill their prescriptions more frequently.

Despite the overall positive sentiment about days supply limits, there were concerns with the 14-days supply restriction on antibiotics that were indicated to be used for longer periods of time. One pharmacist stated:

> *I mean, of course it has to be ironed out. Yeah, but there are some things that have just been overlooked in terms of what they are used for. Like antibiotics, 14 days, just across the board.*

Pharmacists' process evaluation

Lack of dissemination. The first concern the pharmacists had about the process of policy implementation was the lack of knowledge that beneficiaries appeared to have about the policy. When the policy was introduced, many pharmacists expressed that they spent a great deal of time explaining the copayment when a prescription was filled. Each pharmacist agreed AHRE should have disseminated information about the policy differently so that patients possessed a greater understanding of it. The pharmacists also believed that they continued to spend a portion of their time explaining the policy to AHRE clients. One pharmacist said:

> *And I don't know if when this (the policy) was proposed to them, if that little piece of paper that came with their cheque just didn't explain it to them or it was just a matter of understanding but some of them- about 50% of my patients, every single time, I have to explain.*

Another pharmacist reinforced the lack of understanding of the policy by saying:

> *Yeah, well we pasted it (AHRE policy explanation) right on our counter, where they see it, I mean everyone's like, I don't understand. But yeah, it's so frustrating. I mean day in and day out it happens. How many times?*

These findings suggest that pharmacists remain concerned about the dissemination and perhaps even the understanding that AHRE clients have about the copayment policy. There were also concerns among four pharmacists in the group that the manner in which the copayment allowance on their cheques was marked, made it difficult for beneficiaries to understand. For example, the pharmacists interviewed believed that the additional $5 allowance was simply labeled copay allowance, which may have been ambiguous to AHRE clients. When pharmacists tried to collect the copayment, the patients were not cognizant that they had already received monetary compensation for the purchase of prescriptions on their monthly cheques.

Charging the copay. Perhaps the greatest concern for all of the pharmacists was charging the copayment to their clients. The pharmacists resented having to enforce the policy by administering the copayment for several reasons. Pharmacists were faced with feelings ranging from guilt about collecting money from impoverished individuals to anger about being repeatedly asked to waive the copayment by individuals they perceived to be irresponsible. These feelings were amplified by the frustration that the pharmacists felt that some pharmacies were waiving the fee for their AHRE clients.

Each of the pharmacists in the focus group worked in pharmacies that made it a policy to charge the copayment to their AHRE clients. Despite this, there were times that the pharmacists felt compelled to waive the copayment. Pharmacists expressed that there were two levels of policy execution. The first level was the policy enforced by the pharmacy itself requiring pharmacists to either waive or charge the fee. As none of the pharmacists admitted to practicing in pharmacies that made it a policy to waive the fee, their opinions for reasons why this might occur were conjecture. However, those pharmacists interviewed stated that the main reason for having a policy to waive the copayment was to generate business. The second level of policy execution was the individual pharmacists' behavior. For example, it may be a store policy to charge the fee, but an individual pharmacist may choose not to do so. The pharmacists believed that correct implementation of the policy was essentially the responsibility of the individual pharmacist. One pharmacist concluded by saying,

> *And it's basically the onus of the pharmacist to collect the two dollars, and a lot of these people are irresponsible with their money, and they are going to show up with their prescription, don't realize that they have to pay anything, yet they need the prescription. So you are left with the decision about whether to give it to them, and you know, count on them to come back and pay it. But there are always going to be the people that you will never see again. And you lose that two dollars.*

All of the pharmacists interviewed stated that it was difficult to collect the copayment from a great number of their AHRE clients. Patients often gave several reasons for why they did not want to pay the two dollars that ranged from not having the funds to do so to arguing that other pharmacies were waiving the fee. This frustration often created uncomfortable situations for pharmacists where they felt guilty about the manner in which they treated patients differently. One pharmacist expressed her inner struggle with charging the copayment to an individual when she said:

> *When we first started we had a lot of people arguing, but we also had a lot of, like, hard luck people. Hard luck cases that would come in and say, "Look, I really need this five dollars, could you, you know, I need my prescriptions, could you waive this fee? Do I have to pay it?" And you know, what do you say to those people. You know, I am sorry. I have to collect the two dollars but you could really tell that they needed it, you know?*

The entire group of pharmacists who participated in the focus group interview were simply annoyed by the fact that they were the ones having to enforce the policy. One pharmacist said:

> *And I don't think it's fair. Because we get yelled at on a regular basis for any little thing, you know. We don't need this (the policy) to add to it.*

Another pharmacist added:

> *We feel like we are on the front lines, like we are the ones that have to explain it. We are the ones that have to collect it. And we are the ones who get the flack for it.*

This feeling of frustration also caused some of the pharmacists to take out their annoyance on clients that may not have deserved such treatment. This type of situation caused pharmacists to resent the policy even more. One pharmacist related one such experience:

> *Well, I mean you just run into so many situations... You see the lady and gentleman with the two kids, you know, the two small kids and then you see the person right beside them abusing the system. It just plays on you so much, like it just builds your frustration. You get to the point when you are snapping at the wrong people, you know, you are just getting those really hard luck cases that really, and really don't have the two dollars to pay. "Can I come back next week?" And you are just like going NO!. Like you're just, ... you're fed up and I mean, it's just like I said, puts us in a tight spot because you don't want to be the bad guy. I mean, I am supposed to be there to provide care for them, not to be this mean banker lady who has to collect this measly two dollars.*

Evasion of the policy. The pharmacists interviewed were also privy to a number of methods by which both pharmacists and clients avoided complying with the policy. Pharmacists told about a number of ways in which they can be non-compliant with the policy. In addition, they had first-hand observation of a number of means by which clients had avoided paying the copayment each time they filled their prescriptions.

Changing the directions for use slightly to reflect prn or as needed dosing schedules would allow pharmacists to increase days supply at their discretion. Another possibility was the use of the directions, "take as directed", which gave the practitioner some discretion in how much medication they could dispense at each visit.

Pharmacists greatest concerns were the evasion of the required copayment for prescription medications. Each pharmacist shared a story of pharmacies that waived the fee on a regular basis. This was frustrating for the pharmacists as they felt that they were being financially penalized by complying with the policy, when AHRE clients expressed to them that other pharmacies would not charge them. One pharmacist said:

> *I'm worried about those stores that actively waive the two dollar fee. 'Cause we have clients that claim they shop around, or they say, "You charge me the two dollars, I'll go somewhere else where they won't." You know, so there has to be places out there that aren't charging this two dollars.*

Surprisingly, one pharmacist suggested that the waiving of fees was so rampant that even AHRE employees were encouraging beneficiaries to seek out those pharmacies that would waive the fee. That pharmacist stated:

> *I have seen people who are wondering to find out what are the other competitors... were they waiving that or not. And some of the social workers might have said it at the time that you shop around, some pharmacies may not charge you that.*

Evasion of the policy was not limited to the discussion of those committed by health care professionals. The majority of pharmacists suggested that beneficiaries had a variety of ways of avoiding the policy. One way to do so was to have the first three prescriptions each month filled at a different pharmacy, not pick them up and then go to another pharmacy to have additional prescriptions filled. The pharmacists considered this method to be quite effective because the pharmacy that filled the first prescriptions would likely not reverse the charges for at least a few days. One pharmacist describes such a scenario:

> *Technically, you could go to a doctor, get three scripts and mean nothing to them. You know, other scripts will be sitting in the bin, they'll go get their fourth prescription which they will want and they'll get off scot-free.*

A second, but less successful method of avoiding the policy was to have a series of prescriptions filled at the pharmacy, but only choose to pick up the ones that had no charge. This type of evasion requires pharmacists to reverse all the prescriptions and put through the medications that the individual wanted in the correct order to ensure that the beneficiary pays the required copayment. Often, the pharmacist may inadvertently miss this type of policy evasion.

Pharmacists' Impact evaluation

During the interview, pharmacists also expressed some of their opinions about the impact that the policy has had on their patients. First, pharmacists in this focus group did not believe that the policy improved the responsibility and accountability of AHRE clients. One pharmacist said:

> *They might have done it to show that they were getting something of value, to make them value it more. But it doesn't seem to have worked. They don't seem to appreciate, your medication costs eighty dollars, you're paying two dollars. It's not very much, but they still don't seem to realize that they're...you know, it doesn't increase the value of what they are getting.*

Pharmacists also believed that the policy might have negatively impacted the wrong individuals. In other words, the individuals who were responsible with their money were the ones truly hurt by the policy, while those who abused the system were not affected by it. A pharmacist illustrated this point by saying,

> *I do have people who do not have a problem with paying. They completely understand it. It's almost in a way the abusers are not even getting burned by the system. Like they are not even learning. And it's the ones who get the one antibiotic a month that are really suffering. Yeah, really paying for it, you know.*

Pharmacists final concern about the impact of the policy was the possibility of non-compliance with prescribed medication regimens. This concern was associated with the belief that the policy may have punished responsible individuals rather than those who frequently abused the system. One pharmacist spoke of scenarios she had frequently seen in her pharmacy.

> *You see the mom's coming in with the scripts for the kids and putting one of them in her purse. I mean, whether it's an antibiotic or an antidepressant or whatever it is just because they know. That's two dollars they can use to buy food.*

Another pharmacist discussed the concerns about individuals not taking medically essential medications because of the copayment.

> *I know I am going to have to pay the two dollars and I know I need certain medications, but I really want other medications, so you'll see them drop off on compliance and take the ones they want like T-threes in some cases and kind of like you say, about the heart medicine.*

Summary

The results from the focus group interview suggest that pharmacists believed that the policy did not produce the impact that AHRE intended. They believed that there may have been shortcomings in the dissemination of the policy that have caused patients to either not hear about the policy or not understand its intricacies. In general, pharmacists resented having to enforce the policy and experienced some emotional conflict by being forced to collect the copayment from their patients. This resentment, coupled with the fact that many of the pharmacists felt the policy was not affecting individuals who abuse the system created a great deal of frustration. The additional knowledge that many pharmacies were waiving the fee further aggravated the pharmacists. Each pharmacist cited different mechanisms by which pharmacists and beneficiaries could evade the policy.

Those interviewed believed that the policy might have negative consequences for individuals who are trying to make ends meet, as individuals either choose not to fill prescriptions or selectively fill them. They also suggested that the policy may not be having any impact on drug abusers by curtailing their medication use. In addition, the policy changes did not appear to be teaching AHRE beneficiaries fiscal responsibility.

Phase 2- Survey of Alberta Community Pharmacists

This section will present the results of the mail survey of Alberta community pharmacists' opinions about the changes to the Alberta Human Resources and Employment drug policy as well as their attitudes toward social services clients. Initially, pharmacist demographics will be used to describe the sample. Second, the development of constructs from the survey items will be discussed. Third, differences in pharmacists' attitudes and actions based on demographic data will be explored. Finally, qualitative comments from respondents to illustrate their opinions are presented.

Results

A response rate of 73.5% (n=355) was achieved. Table 3 contains the demographic data of the respondents. The majority of the respondents were female (58.6%). The pharmacists were a mean age of 38.55 years (± 10.14) and had practiced for an average of 14.75 years (± 10.2); 44.3% of respondents had practiced for 10 years or less. The majority of pharmacists practiced in independent pharmacies (45.1%) and 42% were owners/managers. A mean of 17.3% (± 14.3) of the pharmacies' patients were social services clients. The majority of respondents (71.8%) practiced for greater than 31 hours per week.

Table 3: Demographic data of pharmacist survey respondents (n=355)

Demographic Variable	Frequency[1](%)
Age	
20-35 years	157 (46.0)
36-50 years	133 (39.0)
older than 50 years	51 (15.0)
Sex	
Male	145 (41.4)
Female	205 (58.6)
Practice Setting	
Chain	100 (28.7)
Grocery/Retail	91 (26.1)
Independent	157 (45.1)
Pharmacist's role	
Owner/manager	147 (41.9)
Staff pharmacist	204 (58.1)
Hours worked weekly	
10 hours or less	21 (6.0)
11 to 20 hours/week	36 (10.3)
21 to 30 hours/week	42 (12.0)
31 to 40 hours/week	141 (40.2)
greater than 40 hours/week	111 (31.6)
Length of time practicing	
0 to 10 years	155 (44.3)
11 to 20 years	96 (27.4)
21 to 30 years	73 (20.9)
31 to 40 years	23 (6.6)
greater than 40 years	3 (0.9)
% Social Services Clients	
0% to 50%	316 (94.3)
greater than 50%	19 (5.7)

[1] Sum of frequencies may not equal 355 due to missing data.

Store policy.

Focus group data suggested that some pharmacies consistently waived the copayment for their social services clientele. The final question on the survey was intended to address the issue by asking pharmacists directly if it was their store policy to waive the fee. Figure 1 shows that a very small number of the pharmacists (3.1%)

indicated "yes" to the question labeled pharmacy compliance, thereby indicating that it was their pharmacy's policy to waive the copayment for social services clients.

Instrument Analysis- construct development

The original survey instrument contained a total of 41 items. Forty of these questions possessed Likert scale (1 to 5) response options where 5 indicated greater agreement or congruency with the policy. One question was removed from the consideration because of the negative feedback from the respondents. Comments from respondents suggested that this item was difficult to answer, as it appeared to contain two ideas.

Table 4 describes the original grouping of items within each hypothesized construct, item-total correlations and their initial reliabilities. The first construct, named 'Policy Administration', contained items that addressed Alberta Human Resources and Employment's administration of the policy. It addressed the global administration of the policy. The second construct was labeled 'Policy Impact' and contained items that addressed what pharmacists believed the impact of the policy would be on social services clients. The third construct was named 'Pharmacy Administration' and dealt with the issues surrounding the implementation of the policy within each individual pharmacy. The fourth construct was labeled 'Policy Compliance' and dealt with the individual pharmacists' compliance with the policy in their pharmacy. It must be noted that this construct deals directly with the individual pharmacist's behavior within the pharmacy and is separate from the question addressing whether or not it was a store policy to waive the co-pay. The final construct addressed pharmacists' opinions of social services clients and was labeled 'Perceptions of Social Services Clients'.

Table 4: Original construct groupings and reliabilities*

Construct Name	Item	Item Description	Item-total correlation	Construct Reliability
Policy Administration	1	Most social services patients have not been well informed about the drug plan changes.	0.2392	0.63
	2	In general, most doctors are aware of the drug plan changes.	0.1860	
	4	Social services drug plan changes were put in place to prevent medication wastage.	0.1821	
	6	Adult social services clients should not receive the extra $5.00 per month to partially cover medication expenses.	0.0865	
	7	The days supply limits are reasonable.	0.2170	
	8	The $2.00 co-pay per prescription is too much for social services patients to pay for medications.	0.4388	
	9	A percentage co-pay would be better than the $2.00 copayment.	0.0386	
	10	I think the $2.00 copayment is reasonable.	0.5418	
	25	Pharmacists should work together to have the $2.00 co-pay removed because it is unfair to social services clients.	0.4754	
	26	Pharmacists should work together to have the $2.00 co-pay removed because it is too much of a burden for pharmacists to administer.	0.4735	
	33	I have to explain the drug plan to the majority of social services patients.	0.3498	
Policy Impact	11	The drug plan changes have been successful in helping social services patients be responsible for their money.	0.3925	0.54
	12	The drug plan changes have been successful in preventing individuals who abuse medications from accessing as many prescription drugs.	0.2879	
	14	The drug plan changes prevent social services patients from getting the essential medications (e.g., antihypertensives) that they need.	0.3771	
	15	The drug plan changes have caused real financial hardships for my clients.	0.3505	
	17	The drug plan changes encourage individuals to be more responsible for their health care expenses.	0.4239	
	18	The drug plan changes act as an incentive for social services patients to avoid getting prescriptions.	0.2047	
	19	The drug plan changes have been successful in helping social services patient become aware of the cost of medications.	0.3211	

Table 4 cont'd

Pharmacy Administration	3	Pharmacists should be provided with written material to assist them in explaining the drug plan changes to social services patients.	0.0804	0.60
	5	Instead of drug plan changes to control costs for social services patients, pharmacists should be paid to provide pharmaceutical care for them.	0.0944	
	20	Pharmacies should have the right to waive the $2.00 fee if they want.	0.5808	
	21	The work required to administer this plan in my pharmacy is no different than the work required to administer any other plan (e.g., Assure, Alberta Seniors Drug Plan)	0.2121	
	22	Pharmacies should be policed in some way to ensure that they are following the drug plan.	0.4667	
	23	There should be penalties for pharmacies that violate the drug plan that requires social services patients to pay $2.00.	0.6320	
	24	The variability with some pharmacies charging the fee and others not charging it is good to promote competition between pharmacies.	0.3100	
Perceptions of Social Services Clients	27	In general, I understand what social services patients are going through.	0.1574	0.74
	28	Most social services patients are just trying to use the system.	0.5255	
	29	The majority of social services patients are trying to "get back on their feet" and get off social services.	0.5799	
	30	In general, I believe that social services patients are irresponsible with their money.	0.6552	
	31	There are only a small percentage of social services patients that are abusing the social services system.	0.5855	
	32	Social services patients need to be responsible for their money.	0.4052	
Policy Compliance	13	The majority of social services patients find ways of avoiding payment of the $2.00 co-pay.	0.3960	0.56
	34	I charge the $2.00 copayment to my social services patients.	0.3675	
	35	I am afraid to enforce the policy because I feel physical harm might come to me.	0.4942	
	36	It is hard to collect the required copayment from my social services patients because I feel sorry for them.	0.4463	
	37	It is hard to collect the required copayment from my social services patients because they always argue with me about it.	0.4697	
	38	We allow social services patients to 'run a tab' for their medication copayments.	0.1865	
	39	I work with my social services patients to create a payment plan for unpaid copayments that is amenable to both of us.	-0.4234	
	40	I find ways of giving more than the days supply limit to my social services patients.	0.2658	

* Cronbach alpha

After the initial grouping of items into the hypothesized constructs; Cronbach alpha values for each of the constructs were calculated. Ten items were deleted from the constructs to improve their internal consistency. Table 5 describes the final constructs, their associated items and Cronbach alpha reliabilities.

Table 5: Final construct groupings and reliabilities*

Construct Name	Item Number	Item Description	Item-total correlation	Construct Reliability
Policy Administration	1	Most social services patients have not been well informed about the drug plan changes	0.2868	0.70
	2	In general, most doctors are aware of the drug plan changes.	0.1978	
	7	The days supply limits are reasonable.	0.2227	
	8	The $2.00 co-pay per prescription is too much for social services patients to pay for medications.	0.5716	
	10	I think the $2.00 copayment is reasonable.	0.4592	
	25	Pharmacists should work together to have the $2.00 co-pay removed because it is unfair to social services clients.	0.5846	
	26	Pharmacists should work together to have the $2.00 co-pay removed because it is too much of a burden for pharmacists to administer.	0.5480	
	33	I have to explain the drug plan to the majority of social services patients.	0.3336	
Policy Impact	11	The drug plan changes have been successful in helping social services patients be responsible for their money.	0.6123	0.77
	12	The drug plan changes have been successful in preventing individuals who abuse medications from accessing as many prescription drugs.	0.5120	
	17	The drug plan changes encourage individuals to be more responsible for their health care expenses.	0.6203	
	19	The drug plan changes have been successful in helping social services patient become aware of the cost of medications.	0.5474	

Table 5 cont'd

Pharmacy Administration	20	Pharmacies should have the right to waive the $2.00 fee if they want.	0.6125	0.70
	21	The work required to administer this plan in my pharmacy is no different than the work required to administer any other plan (e.g., Assure, Alberta Seniors Drug Plan)	0.1621	
	22	Pharmacies should be policed in some way to ensure that they are following the drug plan.	0.5845	
	23	There should be penalties for pharmacies that violate the drug plan that requires social services patients to pay $2.00.	0.7061	
	24	The variability with some pharmacies charging the fee and others not charging it is good to promote competition between pharmacies.	0.3281	
Perceptions of Social Services Clients	28	Most social services patients are just trying to use the system.	0.5562	0.78
	29	The majority of social services patients are trying to "get back on their feet" and get off social services.	0.5928	
	30	In general, I believe that social services patients are irresponsible with their money.	0.6559	
	31	There are only a small percentage of social services patients that are abusing the social services system.	0.5799	
	32	Social services patients need to be responsible for their money.	0.4302	
Policy Compliance	13	The majority of social services patients find ways of avoiding payment of the $2.00 co-pay.	0.3992	0.72
	34	I charge the $2.00 copayment to my social services patients.	0.3517	
	35	I am afraid to enforce the policy because I feel physical harm might come to me.	0.4979	
	36	It is hard to collect the required copayment from my social services patients because I feel sorry for them.	0.4986	
	37	It is hard to collect the required copayment from my social services patients because they always argue with me about it.	0.5200	
	38	We allow social services patients to 'run a tab' for their medication copayments.	0.3623	
	40	I find ways of giving more than the days supply limit to my social services patients.	0.3356	

* Cronbach alpha

Construct analysis results

Table 6 describes the respondents' mean scores on each of the revised constructs (i.e., from Table 5).

Table 6: Survey Construct and Means

Construct Name	**Mean ± SD**	**Median**	**Maximum value**
Policy Administration	27.12 ± 4.90	28.00	45
Policy Impact	13.97 ± 3.32	10.00	25
Pharmacy Administration	18.91 ± 3.73	19.00	25
Perceptions of Social Services Clients	14.72 ± 3.53	15.00	25
Policy Compliance	29.98 ± 3.67	31.00	35

Bivariate Analysis

Preliminary analysis was completed using ANOVA. Examination of the data revealed that the assumption of normality had not been met. In these cases, ANOVA was completed and the standardized residuals examined. Any cases with corresponding residuals greater than +3 or less than –3 were removed from the data set. ANOVA was again completed with the remaining cases and the data examined to ensure that the assumption of normality had been met prior to continuing with the analysis.

Table 7 outlines the results of the bivariate analysis revealed several differences in pharmacists' attitudes toward the social services policy, as well as their compliance with it. Female pharmacists and younger pharmacists appeared more likely to agree with the global administration of the policy and had more negative perceptions toward social services clients. When respondents were divided into different professional positions and defined as either owner/managers or staff pharmacists, additional differences emerged. Staff pharmacists were statistically significantly more positive about Policy Administration and possessed more negative Perceptions of Social Services Clients. Differences in pharmacists' opinions also emerged when pharmacies were grouped by type or volume of social services clientele.

Table 7: Mean scores of survey constructs for demographic variables[1,2]

	Policy Administration	Policy Impact	Pharmacy Administration	Perception of Social Services Clients	Policy Compliance
Age					
20 to 35 years	27.75(4.58)^{3,5}	10.04(2.97)	19.69 (3.30)^{4,5}	13.89 (3.51)^{4,6}	30.77(2.21)
36 to 50 years	27.49(4.37)		18.83 (3.59)	15.23 (3.14)	
older than 50 years	25.83(5.05)		17.90 (3.99)	15.61 (3.69)	
Sex					
Male	26.55 (4.77)^{4}	9.91(3.39)	18.77(3.67)	15.11 (3.53)	30.69(2.13)
Female	27.88 (4.39)				
Practice Setting					
Chain	27.65 (3.98)^{3,7}	9.96 (2.81)	19.90 (3.14)^{4,8}	14.52 (3.52)	31.12 (2.10)^{4,8}
Grocery/Retail	28.24 (4.32)		19.70 (3.27)		31.25 (1.97)
Independent	26.60 (5.01)		18.16 (3.81)		30.11 (2.48)
Pharmacist Title					
Owner/manager	26.71 (4.95)^{3}	9.65(3.29)	19.24(3.75)	15.33(3.36)^{4}	30.75(2.25)
Staff Pharmacist	27.77 (4.20)			14.20(3.52)	
Social Services Client Percentage					
0% to 50%	27.52 (4.53)^{4}	9.87 (3.17)	19.19 (3.53)	14.75 (3.42)^{3}	30.76 (2.24)^{3}
greater than 50%	24.16 (4.51)			12.95 (4.08)	29.31 (2.84)

[1] 1=strongly disagree, 5=strongly agree; higher number indicates more positive attitude
[2] Only mean score reported if no statistically significant difference was found.
[3] Statistically significant differences found at $p<0.05$
[4] Statistically significant differences found at $p<0.01$
[5] Tukey's HSD showed pharmacists greater than 50 years of age were significantly different than 20-35 year olds.
[6] Tukey's HSD showed pharmacists 20 to 35 years old different than those greater than 50 years of age and 36 to 50 years
[7] Tukey's HSD showed grocery/retail pharmacists significantly different than independent pharmacists
[8] Tukey's HSD showed grocery/retail and chain pharmacists significantly different than independent pharmacists

Multivariate analysis

The findings of the preliminary analysis suggested that mean scores on each of the constructs may vary depending on demographic characteristics. Therefore, multivariate analysis was conducted to identify which demographic characteristics contributed significantly to variation in each construct score. Initially, all demographic variables and all two-way interactions were entered into the model. Output was examined to note whether the model itself was significant and then whether any two-way interactions could be considered significant. All demographic variables and any interactions that were significant were included in the final model.

Table 8 outlines the findings of this analysis. These findings suggest that there are significant differences in mean scores in the pharmacy administration construct. Specifically, pharmacists age, practice setting and title contributed significantly to the model. There were no two-way interaction terms that were found to be statistically significant. Pharmacists who were younger, practiced in chain or grocery/retail setting or were owners/managers of the stores, possessed significantly more positive views of the administration of the policy within the pharmacy. Significant differences were also found in the construct measuring pharmacists' perceptions of social services clients. In this multivariate model, pharmacists aged 36 years and older were shown to possess significantly more positive attitudes toward clients than pharmacists aged 20 to 35 years. Finally, significant differences were found in the construct that measured policy compliance. Specifically, pharmacists practicing in retail/grocery or chain pharmacies were more likely to comply with the policy than were pharmacists practicing in independent stores.

Table 8: Multivariate analysis of pharmacist survey

Constructs	Model	Demographic Variables		R^2
Policy Administration	p=0.018	Sex	p=0.096	0.029
		Age	p=0.222	
		Practice setting	p=0.265	
		Pharmacist title	p=0.552	
Policy Impact	p=0.102	Sex	p=0.518	0.014
		Age	p=0.134	
		Practice setting	p=0.103	
		Pharmacist title	p=0.256	
Pharmacy Administration	p=0.000	Sex	p=0.304	0.066
		Age[1]	p=0.012	
		Practice setting[2]	p=0.003	
		Pharmacist title	p=0.015	
Perceptions of Social Services Clients	p=0.002	Sex	p=0.363	0.043
		Age[3]	p=0.004	
		Practice setting	p=0.943	
		Pharmacist title	p=0.174	
Policy Compliance	p=0.024	Sex	p=0.647	0.028
		Age	p=0.977	
		Practice setting[4]	p=0.002	
		Pharmacist title	p=0.231	

[1] Tukey's HSD showed pharmacists greater than 50 years of age were significantly different than those 20 to 35 years of age

[2] Tukey's HSD showed pharmacists practicing in chain or grocery/retail stores were significantly different than those practicing in independent stores

[3] Tukey's HSD showed pharmacists greater than 50 years of age and those 36 to 50 years of age were significantly different than those 20 to 35 years of age

[4] Tukey's HSD showed pharmacists practicing in chain or grocery/retail stores were significantly different than those practicing in independent stores.

Qualitative comments

At the conclusion of the survey instrument, pharmacists were asked to add any additional comments about the policy. Eighty-three of the respondents included comments on their completed surveys. These comments reflect similar themes as the constructs had addressed in the statistical analysis of the survey, add context to the survey findings, and illustrate the variety of opinions that are currently held by practicing community pharmacists in Alberta. The following section presents a select number of comments from the respondents that are representative of themes or ideas given in the comments. These comments are grouped according to the construct that they appear to reflect. Pharmacists' written comments are presented in italicized text.

Policy Administration. A series of comments were identified that were representative the Policy Administration construct. Very few respondents appeared to be in support of the policy's administration. One comment supporting the global administration of the current policy was:

> *I do not think that the co-pay creates more work for pharmacists and I support the days supply limits in the majority of cases. I believe that the current system rewards people who don't need a lot of drugs and that is an excellent way to encourage healthy living. I think that it is a good way to remind people of the cost of prescriptions.*

The vast majority of comments, however, had negative views of the Policy Administration. The idea of days supply limits on medications were criticized when one pharmacist stated:

> *I feel it is inappropriate to put a days supply limit on certain medications. For example, a 31 days supply limit on anti-convulsant medications. Many patients have been on the same anti-convulsant for many years and do not have their medications reassessed at appropriate intervals. In such situations, I feel that a 31 days supply limit is an inconvenience for the patient, as well as more costly for AHRE.*

Other pharmacists voiced their opinions about the days supply limits for antibiotic medications. Concerns ranged from the difficulty that patients and pharmacists experience from filling prescriptions 14 days when an antibiotic is actually intended for a longer period of time (e.g, acne therapy). Others were concerned about the possible negative effects that the policy may have on patient compliance with some therapies. One pharmacist said:

> *I think that the 14 day antibiotic supply policy creates a problem when the physician prescribes the antibiotic for a duration greater than 14 days. One time a physician called and blamed us for not giving a patient a month's worth of antibiotics. I had to explain the policy at that time and we did inform the patient to pick up the remaining quantity. However, the patient forgot and we did not keep track, so the patient did not receive adequate therapy.*

Other pharmacists appeared to be concerned with the copayment and felt that patients may be unnecessarily harmed by such initiatives. For example, one pharmacist stated:

> *We are talking about social services. $6.00 a month vs. $5.00 extra on a cheque is punishing the sickest and neediest of the social services recipients. What kind of*

> *cold-hearted creep thought that one up? If they want to cut back on abuse, then hire a pharmacist to do drug reviews on suspect files.*

Still other pharmacists did not agree with the Policy Administration because they believed that the policy was not sufficient to deter people who abuse medications while it may harm those who honestly require medications. One pharmacist illustrated this point by writing:

> *To curb abuse of the system, there should be a co-pay after a certain number of prescriptions in a month. Also, they shouldn't be given extra money. The abusers get more than three prescriptions a month so a $2.00 co-pay on the first three doesn't deter them. The honest people are being penalized on the other hand.*

A final issue that emerged in the qualitative comments was that the pharmacists felt that the policy was not adequately advertised to social services clients and, therefore they became responsible for explaining the policy to their clients. For example, one pharmacist suggested that:

> *A big help would be to explain to the social services clients what the extra $5.00 is on their cheques is for. That is the government's job- not the pharmacists! I think that it shows up as [on the cheque] as 'co-pay allowance' which a lot of clients don't understand.*

Policy Impact. Pharmacists also expressed opinions about the impact that the policy may have on the social services clientele. All of the comments included some criticism of the policy impact. However, some pharmacists felt that the policy did not "go far enough" while others believed that the policy was too harsh and therefore would negatively impact clients. An example of the former view is illustrated by this pharmacist's comments:

> *The only thing this drug policy did was create problems between the pharmacist and the patient over payment and in the end, the pharmacist lost. Patients are not more responsible for their money. They've just become more creative in finding ways not to pay.*

Another pharmacist believed that the policy was not affecting who it should when they said:

> *The $2.00 is not making a difference for abusers because $5.00 is not an incentive enough to stop abusers but it is an incentive for a mom who needs antibiotics to not get them so that she has an extra $5.00 to feed and clothe her kids.*

Others again illustrated their concerns about non-compliance with essential medications because of the copayment requirement. One pharmacist cited such an example:

> *I know of one person who went without a hypertensive medication for one month because she could not afford it until the following month.*

Pharmacy Administration. Pharmacists also had a significant amount to say about the administration of the policy within pharmacies. Again, these comments appeared to express negative sentiment toward the policy. One pharmacist reflected that issues in policy administration had affected their duties within the pharmacy as they were consistently forced to explain the policy to clients.

> *Social workers should do a better job of explaining the drug charge to clients. This plan has been in place for several years and I am still explaining the $2.00 co-pay. Sometimes I get verbally abused over the policy. The government implemented the changes but I am the one who must explain the policy and then collect the $2.00.*

Another pharmacist indicated his or her resentment over having to collect the co-pay.

> *The co-pay system should be removed. Pharmacists are put in a difficult situation to collect the co-pay. In numerous occasions the patients said that they had no money after the prescription was filled. We had to reverse the transaction because of that. This system only creates frustration for both the patients and the pharmacists. We should not have to make a choice between our financial compensation and the moral obligation to provide the best health care to our patients.*

Social Services client perceptions. The vast majority of comments dealt with pharmacists' perceptions of social services clients. These perceptions ranged from sympathetic to extremely unsympathetic and negative. An example of a comment that expressed sympathy towards clients is:

> *The great majority of social services clients are simply persons in unfortunate situations who, like all of us, strive for betterment of their situation. However, it has been my experience that these people also exhibit strong fiscal irresponsibility and so need education and direction to become productive members of the economy.*

Another comment was:

> *Most people on social services have a lot of things in their life to sort out. Life has been tough for most of them. I hear bits and pieces of their stories. Sad. There are a few people in the system who take advantage of it. I hope they don't spoil it for the rest.*

Again, the majority of the comments received dealing with perceptions of clients tended to be negative. Often these attitudes appeared to emerge from the pharmacists' personal experiences with the clientele. One pharmacist stated:

> *There has to be a better screening process to determine who is eligible. It's infuriating when people on social assistance tell me to "hurry up" their prescription because they have a cab waiting. How can they expect me to feel sympathetic when they complain about $2.00 when they take a cab and have it wait outside. I am not saying that there aren't people who really need help to "get back on their feet" – I'm just saying that there are way too many people who take advantage of the system.*

Other comments were overtly hostile toward the social services clients. One pharmacist wrote:

> *Maybe if we stop giving people free money in this country, those of us who work might actually be able to take home some more of the money we EARN!*

Another said:

> *The bottom line is that these people will never be satisfied; they will always want more for nothing. The cure is-Get a job and work for yourself and pay for your own meds and then you will see some appreciation.*

Policy compliance. Pharmacists provided insightful comments about policy compliance. The majority appeared to require the copayment but expressed frustration over the struggle between policy compliance and providing necessary medications to their patients.

> *When asked about waving the fee.... Absolutely no. But I refuse to withdraw services in circumstances where I feel medication is essential (mental problems, diabetes, blood pressure, seizure disorder). They usually come back and pay when they get the money.*

Other pharmacists suggested that they make distinctions between essential and non-essential medications when levying the copayment against clients.

> *I will not refuse to provide services when a client cannot pay for an essential medication. I will refuse when a medication is an abused agent.*

Other pharmacists suggested that patients try to avoid the copayment. One such example follows:

> *When I find it hard to collect the $2.00 fee it is often because a patient has a story/reason why they can't pay right now. "I will be back to pay later" ... Sure. But I don't want to refuse them needed medication. Most of the patients have accepted the reality and pay the $2.00 but some try to worm out of it (I forgot my purse) and I find that very dishonest.*

When it came to store policy's about charging the copayment, it appeared that many pharmacies had a policy of charging it. However, some allowed clients to "run tabs" that were rarely collected, thereby effectively negating the policy.

> *The store's policy is to collect the co-pay but I have stacks and stacks of uncollected $2.00 co-pays each month.*

There were several comments that addressed the concern that requiring the copayment could cause a dramatic decrease in the pharmacy's business. One pharmacist cited an example:

> *At my place of employment, we waive the $2.00 co-pay for patients, although I don't agree with this procedure. I think that because patients get that extra $5.00 specifically for this program, it should be used for this reason- not elsewhere. I have spoken to my manager about this who is afraid to start implementing the co-pay for fear of the response from patients when we "all of a sudden" start requiring them to pay.*

The final comments dealing with policy compliance address the store policy of waiving the copayment. Several pharmacists expressed their frustration that some stores do not comply with the policy. One such comment reads:

> *I have had some customers specifically ask if we charge the $2.00 co-pay. They say that there are stores which waive the co-pay. I don't agree with that! They are getting money from social services to offset that. So why are these pharmacies waving their fees? It sure doesn't look good for our profession.*

Two comments addressed the type of store responsible for waiving the copayment. These comments echo the findings of the quantitative analysis of the survey as well as the focus group findings. One pharmacist said:

> *It is my opinion and experience that the independent pharmacies are the main group not collecting the $2.00 co-pay. It undermines the efforts of the rest of us.*

Yet another supported this comment by writing:

I think it is a laugh that grocery store pharmacists are sometimes considered unethical when it is the independents that waive the fee to make it hard for everyone. Let's call the kettle black.

In summary, qualitative comments from the survey instrument provide context for the quantitative analysis of the survey. Several of the comments serve to provide insight into the behaviors of the pharmacist within their stores, as well as, shed light on the issue of policy compliance.

Phase 3 – Time Series Analysis of Drug Claim Data

Time series models were created to describe the impact that the Alberta Human Resources and Employment drug policy changes had on the utilization and expenditures of specific classes of medications. The first policy that implemented the $2.00 copayment for all prescription medications received by adult social services clients was implemented in November 1997. Drug utilization for two therapeutic classes including angiotensin-converting enzyme inhibitors (24:04:00) and antihyperglycemic agents, divided into sulfonylureas (68:20:20) and miscellaneous antihyperglycemic agents (68:20:92) was examined. The second policy that involved placing days supply limits on specific medications was implemented on February 1, 1998. The impact of this policy combined with the $2.00 copayment requirements was examined by reviewing the utilization of selective serotonin re-uptake inhibitors (28:16:04), anti-manic agents (28:28) and tranquilizers (28:16:08). The following section will describe development of each time series model and the analysis of the impact on the utilization and costs of each of these drug categories.

Policy 1- $2.00 copayment

Therapeutic category 68:20:20- sulfonylureas

Recipients who used therapeutic category 68:20:20 prior to November 1, 1997 numbered 1645 with 48.7% male with a mean age of 56 years (range 19 to 88 years). Recipients included in the post-policy implementation group numbered 1875 with a mean age of 55 years (range 22 to 91) and 49.2% were male.

Number of prescription per100 recipients per month

The impact of the $2.00 copayment was first examined by describing the possible changes in utilization of sulfonylureas. Data was collected from May 1996 to July 1999. Figure 1 is the graphical representation of the number of prescriptions per 100 recipients per month throughout this time period. Policy 1 was implemented on November 1, 1997. The mean number of prescription per 100 recipients per month was 132 prior to the policy being implemented. A qualitative review of the graph suggests that the policy had little effect until approximately two months after it was implemented. At that time, a decrease in the number or prescriptions obtained was evident. This trend continued until April 1998 at which time utilization appeared to increase gradually. The mean number of prescriptions after the policy was implemented was 150. This would suggest that the $2.00 copayment had little effect on the utilization of sulfonylureas over the long term.

A time series model to describe the utilization of sulfonylureas prior to and following the implementation of the $2.00 copayment was developed. The following model described the impact that the $2.00 copayment had on the utilization of sulfonylureas:

$$Y_t=3Y_{t-1}-3Y_{t-2}+Y_{t-3}+2.56-10.06X_{t-3}+10.75X_{t-5}+a_t$$

The overall average number of new prescriptions per 100 recipients per month after the policy was implemented was 2.56 when adjusted for the first three months post-policy. Three months after the policy was implemented, a decrease of 10.06 prescriptions per 100 recipients per month was realized. This decrease in prescription use reached statistical significance (p=0.007, 95% CI –17.14,-2.98, SE 3.49).

It is evident from the examination of this data that a transient, but significant decrease in the utilization of sulfonylureas occurred after the implementation of this policy. However, after April 1998, the utilization of this class of medications began to increase and continued this upward trend until the study's conclusion. The information presented suggests that a decrease in utilization did occur within three months of the introduction of the \$2.00 copayment, however this decrease was not maintained. Therefore, the policy appeared to have marginal to no long-term impact on the number of prescription filled for this type of medication.

Dollars per 100 recipients per month

Figure 2 describes the utilization of sulfonylureas in terms of dollars/100 recipients/month. The dollar values represent the costs incurred by Alberta Human Resources and Employment in paying for these medications for their clients. The mean cost per 100 recipients/month incurred by AHRE for this class of medications was \$2,363.00 prior to the policy being introduced. From the graph, one can observe that there was a transient decrease in utilization followed by two transient increases in utilization in January 1998 and April 1998. After that time, there is a gradual decreasing trend until the study's conclusion. The mean cost per 100 recipients/month after the \$2.00 copayment was implemented was \$2,218.63.

The model was described by the following equation:

$$Y_t = 3Y_{t-1} - 3Y_{t-2} + Y_{t-3} - 47.10 - 139.53X_{t-1} + 173.01X_{t-2} + a_t$$

The mean decrease in dollars/100 recipients/month after the policy was introduced was \$47.10. One month after the policy was implemented a non-significant decrease of \$139.53 per 100 recipients occurred (p=0.0969, 95% CI –305, 25.94, SE

81.52). Two months after the policy was implemented, a significant increase of $173.01 occurred (p=0.0419, 95% CI 7.54, 338.38, SE 81.52.

It is evident from the examination of this data that a short-lived and non-significant decrease in costs was incurred by AHRE one month after the policy was introduced which suggests that the policy did not impact drug costs. Despite a decreasing trend in drug costs over the life of the study, this decrease in expenditures cannot be attributed to the policy alone.

Defined daily doses per recipient per month

Figure 3 describes the trend of ddd per recipient prior to and after the $2.00 copayment was introduced to AHRE clients. The mean ddd per recipient prior to the policy being initiated was 61.2 per patient. Graphically, one can appreciate that the trend in ddd, which indicates that the mean level of defined daily doses per patient, decreased in the month the $2.00 copayment was initiated. However, it is interesting to note that the mean level of ddd per recipient actually increased slightly post-policy to a level of 61.8 ddd/recipient. This would suggest that the $2.00 copayment had a negligible impact on the utilization of sulfonylureas.

The model was described by the following equation:

$$Y_t=3.35Y_{t-1}-5.32Y_{t-2}+5.86Y_{t-3}-4.16Y_{t-4}+1.27Y_{t-5}-0.67+0.42X_{t-3}+a_t-0.35a_t+1.27a_{t-2}$$

After the policy was introduced, a mean decrease in ddd per recipient was 0.67. Three months after the policy was in place a significant increase of 0.42 defined daily doses per person was realized (p=0.6362, 95%CI –1.38,2.22, SE0.88). According to the graphical representation of the series, it appears that the decrease in ddd per recipient is maintained until the end of the study and the copayment did not negatively impact utilization of this class of drugs.

Figure 1: Number of sulfonylureas prescriptions per 100 recipients per month before and after the implementation of the $2.00 copayment

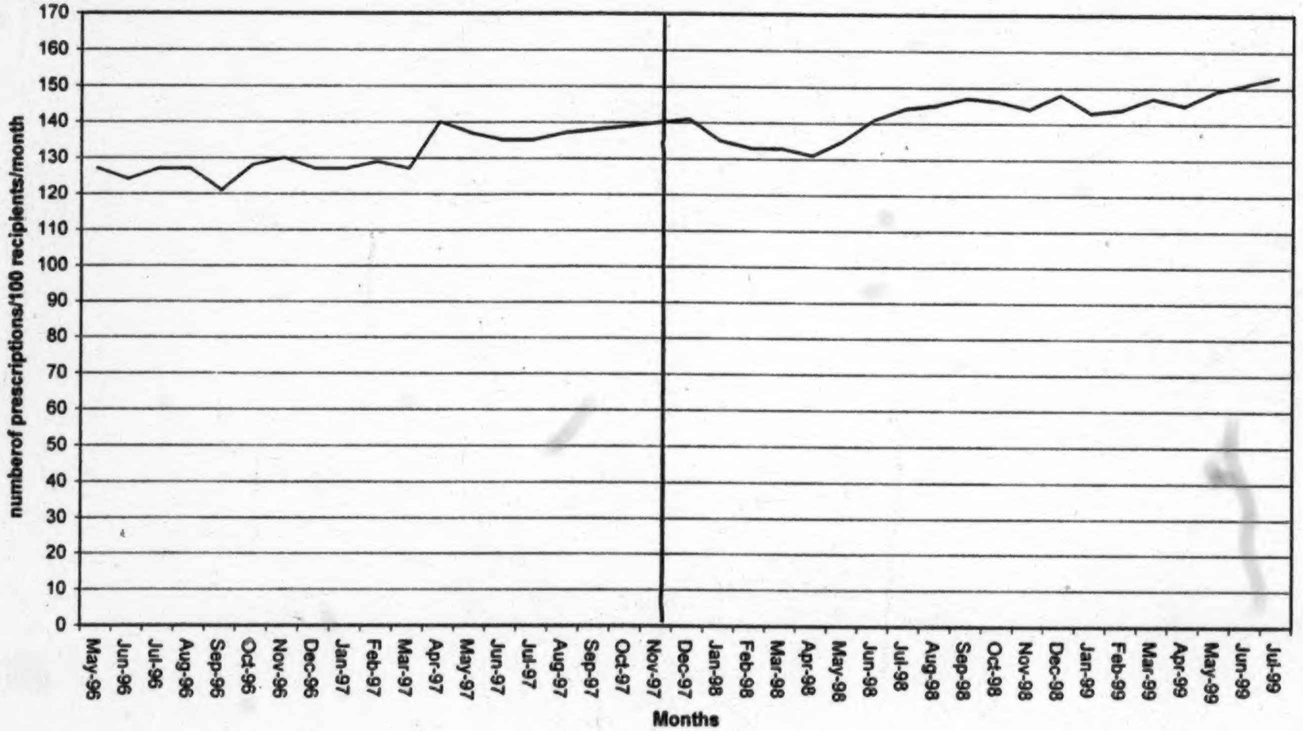


Figure 2: Expenditures on sulfonylurea (68:20:20) prescriptions per 100 recipients per month before and after the $2.00 copayment policy

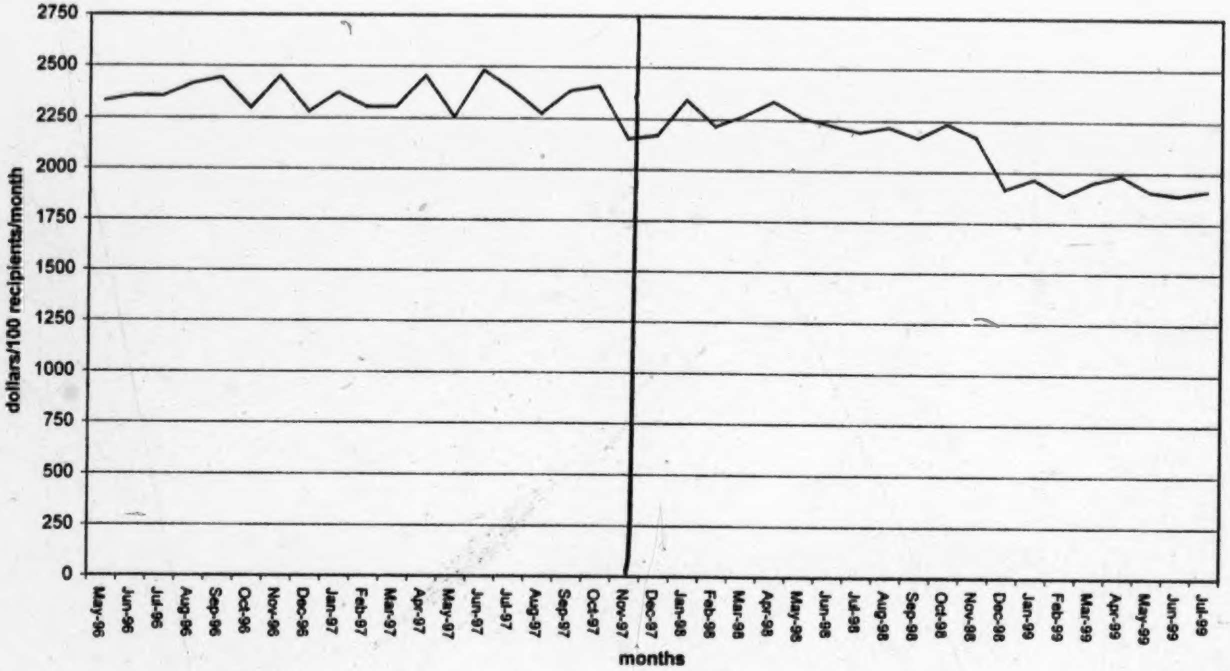
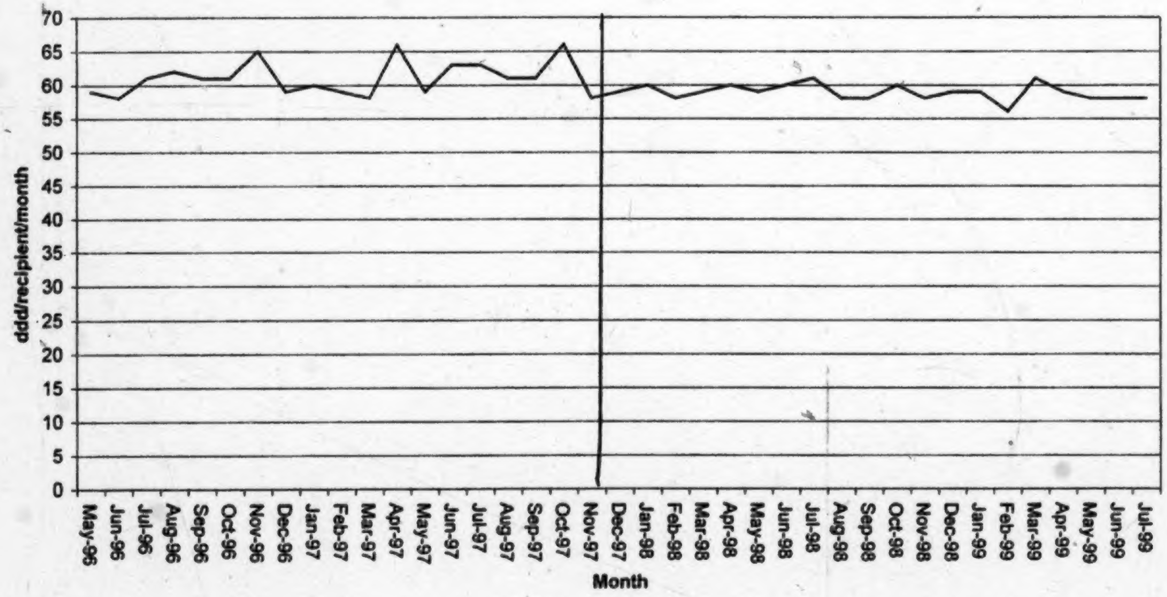


Figure 3: Number of defined daily doses per recipient per month for sulfonylureas (68:20:20) before and after the implementation of the $2.00 copayment



Therapeutic category 68:20:92: miscellaneous anti-diabetic agents

There were 1414 recipients who used therapeutic category 68:20:92 prior to November 1, 1997 with an average age of 55 years (range 19 to 83 years) at the time of service and were 44.1% male. During the period after the policy was implemented, the recipients numbered 1868 with a mean age of 55 years (range 19 to 84 years) and were 44.8% male.

Number of prescriptions per 100 recipients per month

Figure 4 is a graphical representation of the number of prescriptions per 100 recipients per month of miscellaneous anti-diabetic agent prescriptions. The mean number of prescriptions per 100 recipients was 133 prior to the $2.00 copayment being initiated. Graphically, the policy appears to have had little impact on the number of prescriptions that patients acquired for their miscellaneous diabetic medications. In fact, it appears that there is a slight upward trend in the data throughout the time period. However, there appears to be a transient decrease in the number of prescriptions per 100 recipients per month in the first few months of the policy being in place. The mean number of prescription per 100 recipients per month was 155 after the policy was implemented. This would indicate that despite a decrease occurring in the months post policy, the policy did not have a long-term impact on utilization.

This apparent lack of impact of the policy is borne out by the statistical analysis. The following model is a parsimonious description of the utilization trends of therapeutic category before and after the $2.00 co-payment was implemented:

$$Y_t=3Y_{t-1}-3Y_{t-2}-Y_{t-3}+3.35-12.35X_{t-3}+11.65X_{t-4}+a_t$$

The series reflects that utilization was increasing by 3.35 prescriptions per 100 recipients per month post policy. Three months after the policy's implementation the number of prescriptions per 100 patients per month decreased by 12.35 per month ($p=0.008$, 95% CI –21.25,-3.45, SE 4.36).

It is evident from this data that a significant decrease in the number of prescriptions received by AHR&E clients occurred within the first few months of the policy's implementation. Though some decrease in utilization appears to have occurred, the policy had no significant long-term impact on miscellaneous anti-diabetic use as illustrated by the increasing trend in utilization shown in Figure 4.

Dollars per 100 recipients per month

Figure 5 describes the utilization of miscellaneous anti-diabetic use by AHR&E clients prior to and after the implementation of the $2.00 co-payment. The dollar value represents the costs incurred by Alberta Human Resources and Employment in paying for these medications for their clients. Prior to the policy being implemented, AHR&E incurred expenditures of $2,225.22/100 recipients/month. Visual inspection of the series reveals a decrease in expenditures in November 1997. It is evident that there was a slight increase in expenses in the months immediately after the policy was implemented. Despite these fluctuations in the months surrounding the policy, it appears that AHR&E experienced minimal savings that could be attributed to the policy over the long term. The mean level of expenditure post-policy was $2,179.26/100 recipients/month.

The model was described by the following equation:

$$Y_t=1.95Y_{t-1}+3Y_{t-2}+0.15Y_{t-3}-6.3Y_{t-4}-17.84-9.32X_{t-3}+a_t+1.05a_{t-1}$$

AHR&E was incurring an overall decrease in expenditures at a rate of $17.84/100 recipients/month post-policy. Three months following the policy's implementation a decrease of $9.32 per 100 recipients per month occurred. This increase was non-significant with a p-value equal to 0.755 (95%CI –63.67,45.02, SE 29.61).

Defined daily doses per patient per month

Figure 6 describes the trend of ddd per recipient before and after the policy was implemented. Prior to the copayment being initiated, the mean ddd per recipient was 32. Qualitative inspection of the graph suggests that there was an immediate decrease in ddd/patient in November 1997. However, in December 1997 and January 1998, an increase in ddd/patient was seen. Qualitative examination of the series would suggest a slight increase in ddd/patient, despite a series of fluctuations in the variable from January 1998 though July 1999. The mean level of the series post-policy was 35 ddd/recipient indicating that the policy did not have a negative impact on utilization.

The following model is described the trends in the use of biguanides before and after the $2.00 co-payment was implemented:

$$Y_t=0.60-0.70X_t+a_t$$

There was a mean increase in defined daily doses per patient per month of 0.60 post-policy. In the month that the policy was implemented, a decrease of 0.70 ddd/patient occurred, however, this decrease did not reach statistical significance ($p=0.12$, 95%CI –1.58, 0.18, SE 0.43). The statistical analysis indicating a non-significant decrease post-policy, coupled with visual inspection of Figure 6, would suggest that the policy did not negatively affect utilization of this class of diabetic medications.

Figure 4: Number of miscellaneous anti-diabetic agent (68:20:92) prescriptions per 100 recipients per month before and after the implementation of the $2.00 copayment.

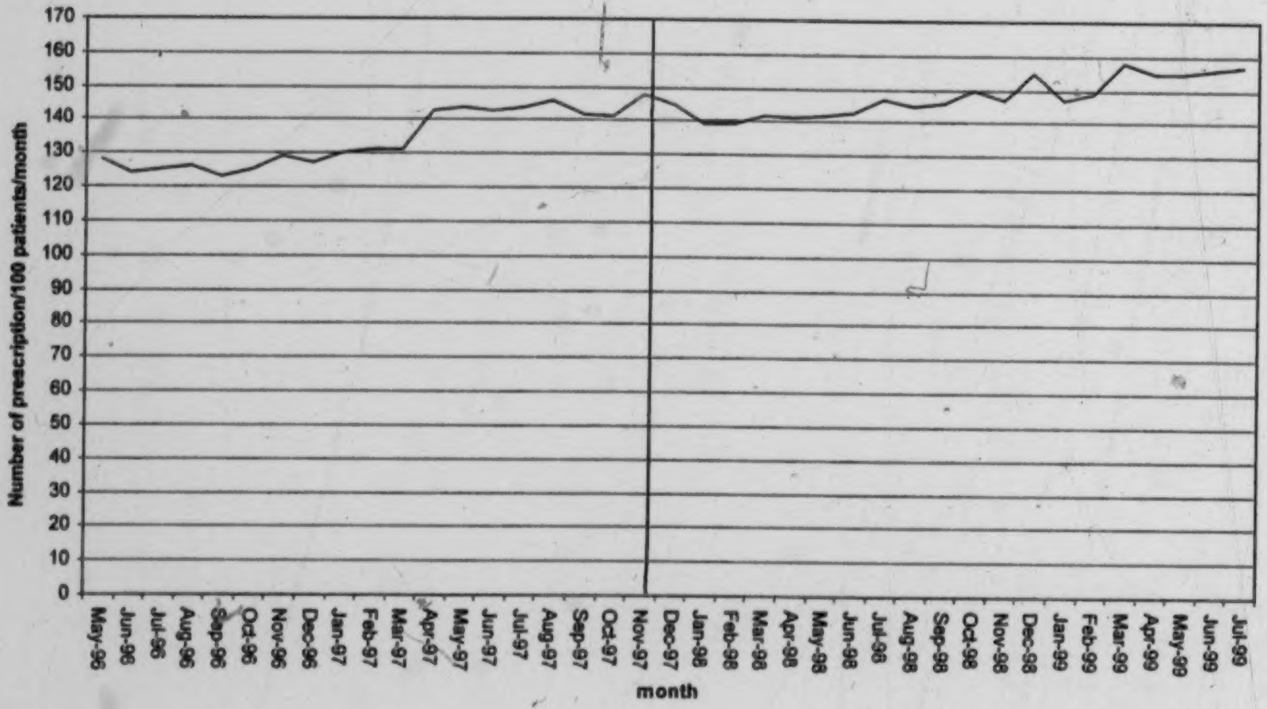


Figure 5: Expenditures on miscellaneous anti-diabetic agents (68:20:92) per 100 recipients per month before and after the implementation of the $2.00 copayment

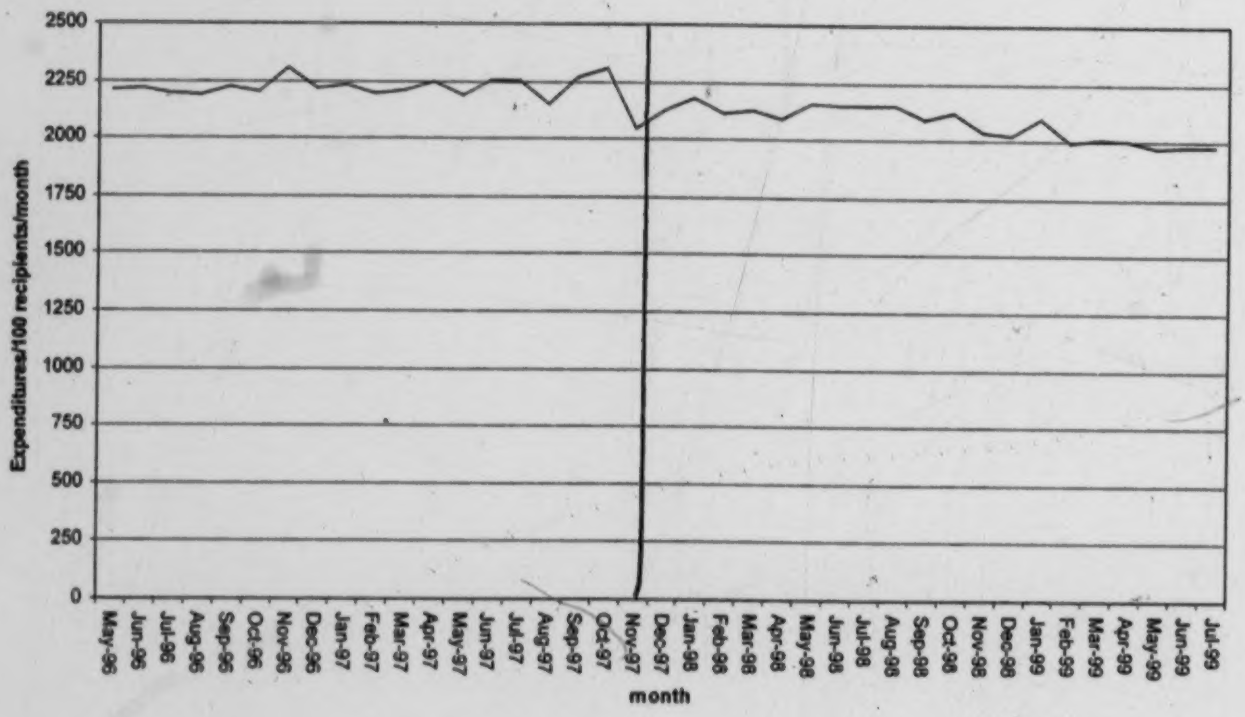
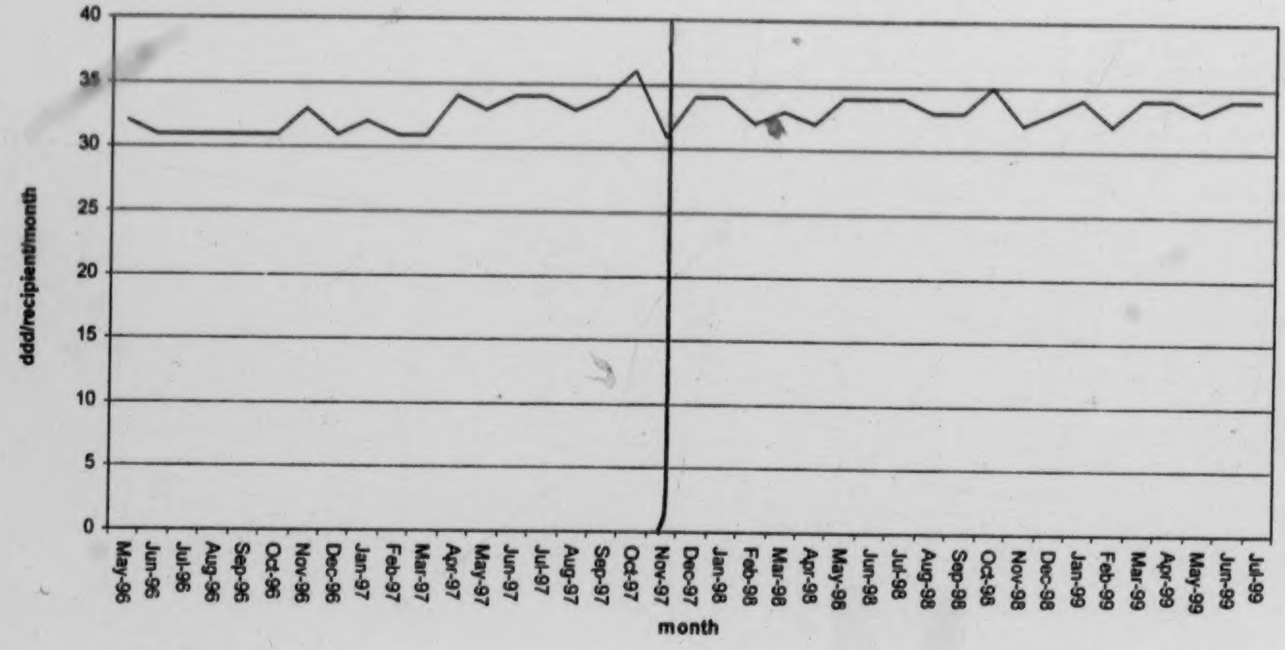


Figure 6: Number of defined daily doses per recipient per month for miscellaneous anti-diabetic agents (68:20:92) before and after the implementation of the $2.00 copayment



Therapeutic category 24:04:00 - ACE inhibitors

Prior to November 1, 1997, there were 3310 recipients who had received prescriptions for this class of medications with a mean age of 55 years (range 19 to 89 years) and were 51% male. After the policy was implemented, there were 3984 recipients with a mean age of 55 (range 18 to 92 years) and were 51.3% male.

Number of prescriptions per 100 recipients per month

Figure 7 is a graphical representation of the number of prescriptions per 100 recipients per month throughout the study's duration. A review of the graph suggests that despite some fluctuations during the months immediately pre and post-policy implementation, the overall trend throughout the series was an increase in utilization. Examination of the mean levels of utilization pre and post-policy would support this assertion as the mean number of prescriptions per 100 recipients pre-policy was 129 and the mean level post policy was 146.

A time series model describing the trends in utilization was developed:

$$Y_t=3Y_{t-1}-3Y_{t-2}+Y_{t-3}+1.44+6.56X_{t-1}-6.47X_{t-2}+a_t$$

There was an average of 1.44 new prescriptions per 100 recipients per month after the policy was implemented. One month after the policy was implemented in November 1997, a significant increase of 6.56 prescriptions per 100 recipients was observed (p=0.0131, 95% CI 1.45,11.67, SE 2.50). Again, it is apparent that the policy did not decrease utilization.

Dollars per 100 patients per month

The impact of the $2.00 co-payment on the Figure 8 is a representation of the expenditures on ACE inhibitors within duration of the study. Prior to the $2.00

copayment being implemented the mean expenditure per 100 recipients was $5,252.30 per month. One can observe that there appears to be an overall decreasing trend throughout the time period with an abrupt decrease in costs incurred by AHRE immediately post-policy. The mean level of expenditure post-policy was $4,902.57/100 recipients/month.

The following time series model describes the impact that the $2.00 co-payment had on the AHRE expenditures/100 recipients for ACE inhibitors:

$$Y_t=3Y_{t-1}+3Y_{t-2}+Y_{t-3}+31.08-619.53X_{t-1}+499.72X_{t-2}+a_t$$

One month after the policy had been implemented, there was a significant ($p=0.007$, 95% CI –956.28, -282.78, SE 164.91) decrease of $619.53 per 100 per month. However, two months after the policy was instituted, an increase of $499.72 per 100 recipients was realized which reached statistical significance ($p=0.0046$, 95%CI 114.59, 834.85, SE 164.14). Due to this fluctuation immediately post-policy, one could conclude that the decrease in cost observed in Figure 8 could not be attributed directly to the policy.

DDD per recipient per month

Figure 9 describes the trend of ddd per recipient over from May 1996 to July 1997. Prior to November 1997 the mean was 60 ddd/recipient/month. One can appreciate that a decrease in ddd/patient occurred during November 1997. However, the variable quickly recovered its increasing trend, and increases in December 1997 and January 1998 were realized. The remainder of the series appears to fluctuate at a slightly higher level than it did pre-policy. The mean level of the series post-policy was 65 ddd/recipient/month.

The following model describes the series:

$$Y_t = -1.67Y_{t-1}+1.28Y_{t-2}-1.82Y_{t-3}-0.52Y_{t-4}+0.73Y_{t-5}+1.632-4.35X_t-4.85X_{t-1}+a_t+$$
$$1.67a_{t-1}+0.73a_{t-2}$$

When the policy was implemented a significant decrease of 4.35 ddd/recipient/month was experienced (p=0.0068, 95%CI –7.38, -1.76, SE=1.49). Despite this decrease, examination of Figure 9 indicates that utilization fluctuated at a slightly higher level post-policy, hence it appears that the $2.00 copayment did not directly affect utilization over the long term.

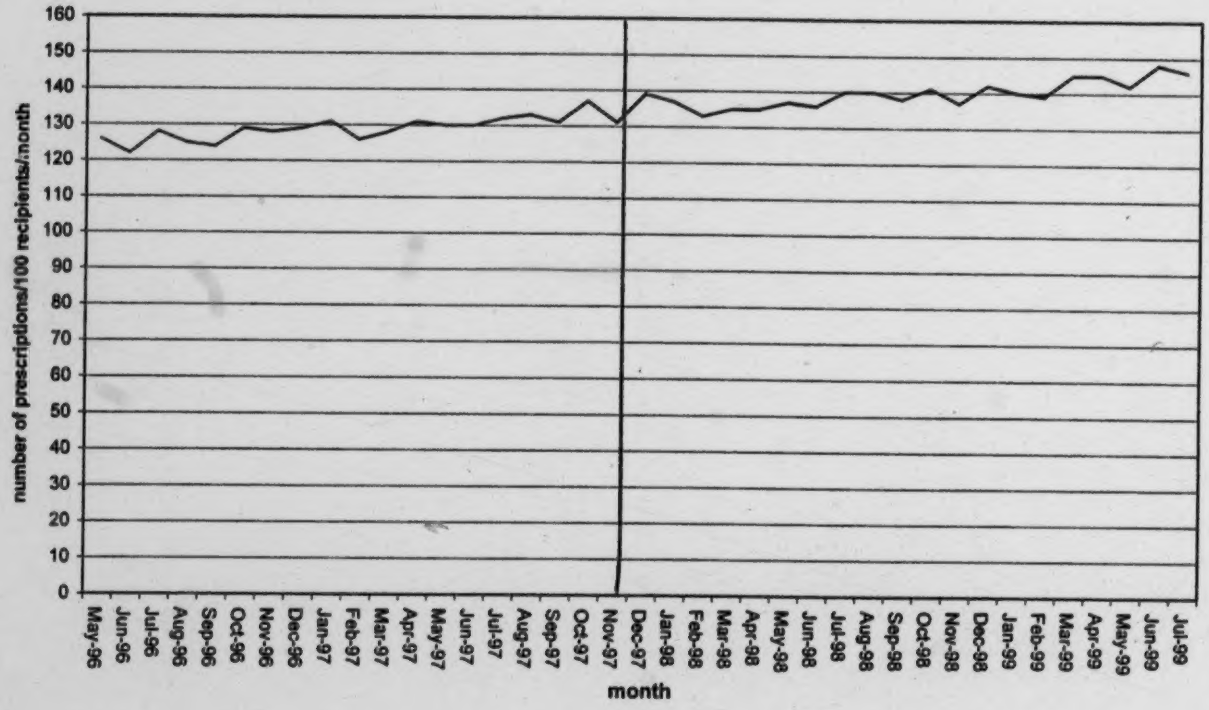


Figure 7: Number of ACE inhibitor prescriptions (24:04:00) per 100 recipients per month before and after the implementation of the $2.00 copayment.

Figure 8: Expenditures on ACE inhibitor (24:04:00) prescriptions per 100 recipients per month before and after the implementation of the $2.00 copayment

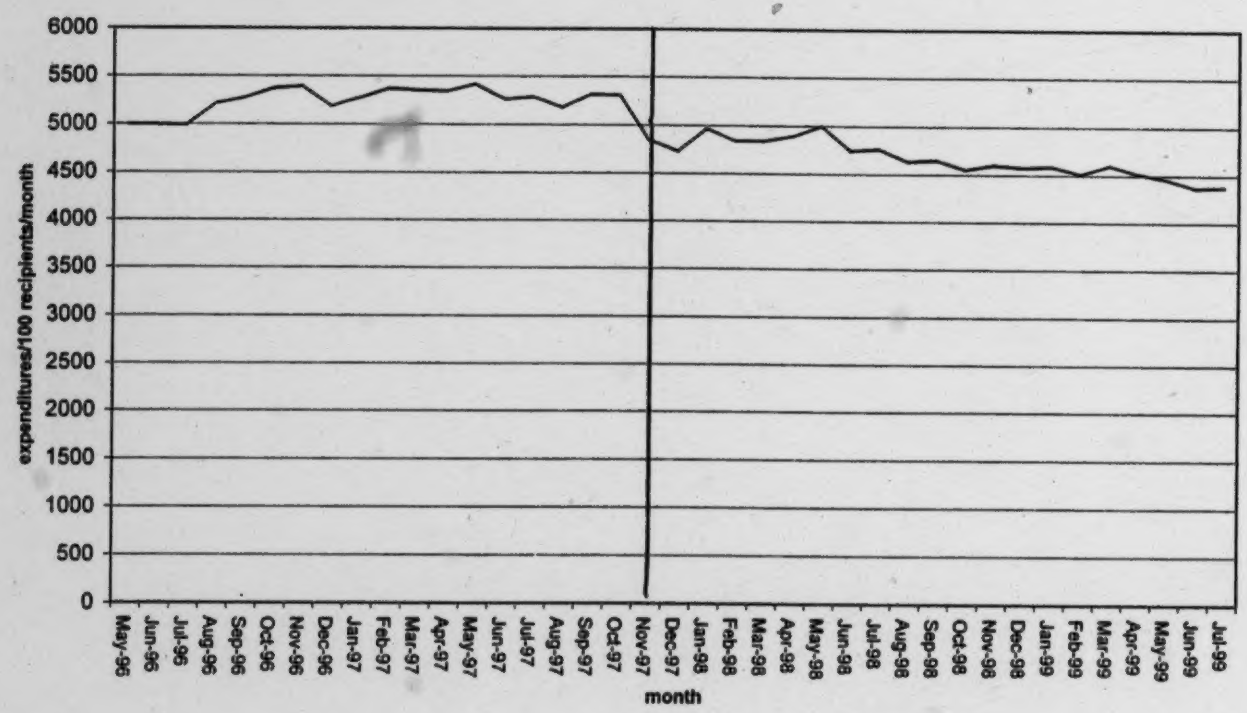
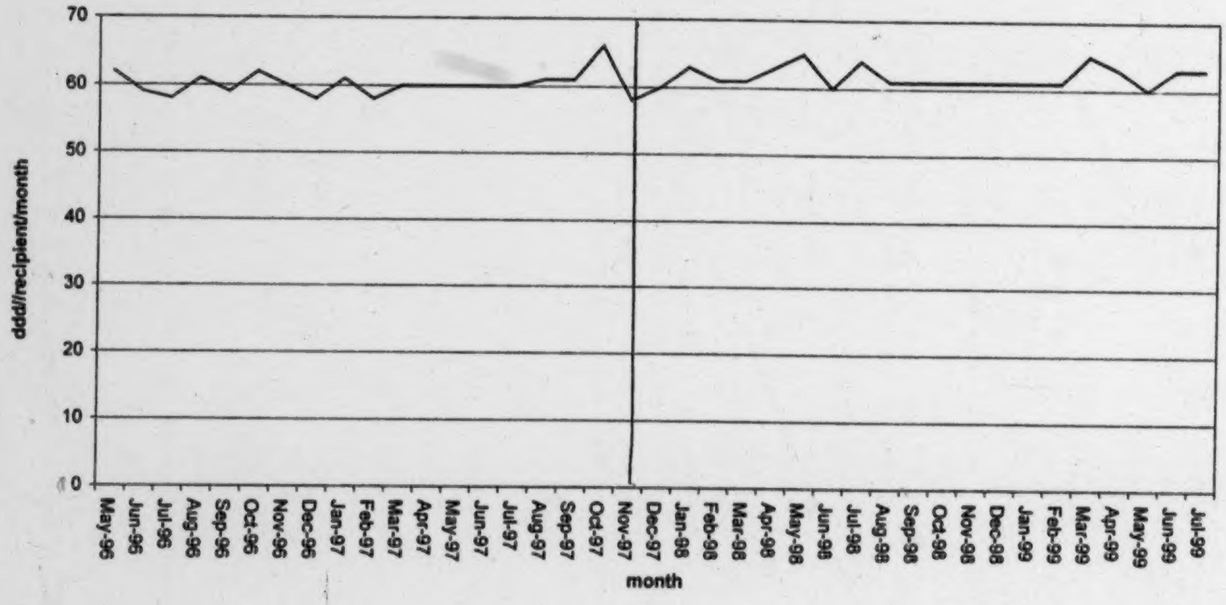


Figure 9: Number of defined daily doses per recipient per month for ACE-inhibitors (24:04:00) before and after the implementation of the $2.00 copayment



Summary of the impact of the $2.00 copayment

In summary, the $2.00 copayment appeared to have little effect on AHRE recipients. Table 9 summarizes the findings of the analysis. All of the classes of medications analyzed can be considered essential medications as they are used to treat chronic conditions that possess negative health consequences. It would be hoped that the utilization of these classes of medications would be maintained despite the implementation of the copayment policy. According to the results of the time series analysis, this appears to be the case. In all therapeutic classes examined, the number of prescriptions per 100 recipients per month showed an increasing trend after the policy's implementation. The AHRE expenditures in therapeutic categories 68:20:20 and 24:04:00 were seen to decrease over the time period, however these decreases cannot be attributed directly to the policy. Finally, ddd/patient was not negatively affected over the long term in the sulfonylureas class of medications despite a significant decrease three months post-policy.

Table 9: The effect of the $2.00 copayment

Therapeutic Category	**Indicator**	**Time series analysis findings**	**Overall trend**
68:20:20 Anti-diabetic agents (sulfonylureas)	Number of prescriptions/100 recipients/month	-10.06 (3 months post-policy) p=0.007 95%CI –17.14, –2.98	increasing
	Expenditures/100 recipients/month	-$139.53 (1 month post-policy) p=0.0969 95%CI –305, 25.94	decreasing
	DDD/recipient/month	0.42 DDD (3 months post-policy) p=0.6362 95%CI –1.38, 2.22	increasing
68:20:92 Anti-diabetic agents (miscellaneous)	Number of prescriptions/100 recipients/month	-12.35 (3 months post-policy) (p=0.008) 95%CI –21.25, -3.45	increasing
	Expenditures/100 recipients/month	-$9.32 (3 months post-policy) (p=0.755) 95%CI –63.67, 45.02	decreasing
	DDD/recipient/month	-0.70 (post policy) (p=0.12) 95% CI –1.58, 0.18	increasing
24:04:00 Cardiac Drugs (Ace-inhibitors)	Number of prescriptions/100 recipients/month	6.56 (1 month post policy) (p=0.0131) 95%CI 1.45, 11.67	increasing
	Expenditures/100 recipients/month	-$619.53 (2 months post policy) (p=0.0007) 95%CI –958.28, -282.78	decreasing
	DDD/recipients	-4.35 (post-policy) (p=0.0068) 95%CI –7.38, -1.32	increasing

Policy 1 ($2.00 copayment) and Policy 2 (30 days supply limit)

Therapeutic category 28:28:00- lithium

Individuals who used lithium prior to November 1997 numbered 1,234 with a mean age of 43 years (range 18 to 75 years) and 45.9% of these recipients being male. After January 1998 the number of patients increased to 1240 with a mean age of 43 years (range 18 to 67 years) and 45.2% were male.

Number of prescription per 100 recipients per month

The impact of the two policies was examined by describing the possible changes in utilization of lithium. Data was collected from August 1, 1996 to July 31, 1999. Figure 11 describes the utilization of this class of medications using the number of prescriptions per 100 recipients. Policy 1 was implemented on November 1, 1997 and Policy 2 was implemented on February 1,1998. Prior to the $2.00 copayment, the mean number of prescriptions per 100 recipients per month was 184. During the three months prior to the 30 days supply being implemented, the mean level of the series was 202 prescriptions per 100 recipients per month. After the 30 days supply limit was in place, the mean level increased to 204. Reviewing the graphical representation of utilization during the study period suggests that there is a general upward trend in utilization. Despite the first policy being implemented in November 1997, it appears that a slight increase in utilization occurred. In February 1998, a decrease in the number of prescriptions per 100 recipients is evident, then an increasing trend appears and continues until July 1999.

A time series model to describe the utilization of lithium during the time period was developed. The following model described the impact that the policies had on utilization of lithium:

$$Y_t = 3Y_{t-1} - 3Y_{t-2} + Y_{t-3} + 183.13 + 20.82X_{t-1} - 0.57X_{t-2} + a_t$$

In December 1997, one month after the copayment policy was implemented, a statistically significant increase of 20.82 prescriptions per hundred recipients was realized ($p<0.001$, 95%CI 13.09, 28.55, SE 3.81). In January 1998, a statistically significant decrease of 0.57 prescriptions per 100 recipients occurred ($p=0.006$, 95% CI –0.87, -0.27, SE 0.148).

It is evident from the examination of this data that the impact of the policies on number of prescriptions per 100 recipients was negligible. An increase in utilization occurred almost immediately after the first policy had been implemented and though a significant drop in utilization then occurred shortly after, an examination of Figure 10 reinforces that a slight upward trend continued until the study's conclusion despite the implementation of the policies.

Dollars per 100 recipients per month

Figure 11 describes the utilization of lithium in terms of dollars per 100 recipients per month. The dollar values represent the costs incurred by Alberta Human Resources and Employment in paying for these medications for their clients. From the graph, one can observe that there is a steady decrease in the dollars per 100 recipients that was spent on this class of medications occurring throughout the study's duration. The mean expenditure was $1605.62/100 recipients/month prior to the $2.00 copayment being implemented and dropped to $1,428.65 in the time between its implementation and the 30 days supply policy coming into effect. After the 30 days supply policy was enacted, the expenditures decreased further to a mean level of $1,378.59/100 recipients/month.

The model was described by the following equation:

$$Y_t=3Y_{t-1}-2Y_{t-2}+Y_{t-3}-37.02-73.97X_{t1}+103.74X_{t2-1}+a_t$$

The mean decrease in dollars/100 recipients/month post-policy was $37.02. In November 1997 a significant decrease of $73.97 per 100 recipients occurred (p=0.008, 95% CI -114.12,-33.82, SE19.78). On month after the implementation of the 30 days supply limit in February 1998, an increase of $103.74/100 recipients per month occurred (p<0.001, 95%CI –65.09, 142.39, SE 19.04). From the analysis it would appear that the introduction of both policies were not catalysts for decreasing expenditures in this class.

Defined daily doses per patient per month

Figure 12 describes the trend of ddd per recipient prior to and after both policies were introduced. The graphical representation suggests that there was an increase in ddd per patient immediately after policy 1 was implemented. Beginning in January 1998 a decrease is evident in the graph and between February and March 1998 it appears that an increase occurred.

The model was described by the following equation:

$$Y_t=3Y_{t-1}-3Y_{t-2}+Y_{t-3}+0.147-1.67X_{t1-2}-1.33X_{t2-2}+3.13X_{t2-3}+a_t$$

Two months after policy 1 was in place a decrease of 1.67 defined daily doses per person was realized, however this decrease did not reach statistical significance (p=0.0751 95%CI –3.5, 0.16). Two months post-policy a decrease of 1.33 ddd per patient occurred, however, it did not reach statistical significance (p=0.4225, 95% CI –4.66, 2.00, SE 1.64).

Using knowledge gained from both the time series model and the graphical description of ddd per patient per month for lithium, one can assert that despite a decreasing trend throughout the time period post-policy, the policies did little to create this decrease.

Figure 10: Number of lithium prescriptions (28:28:00) prescriptions per 100 recipients per month before and after the implementation of the $2.00 copayment and 30 days supply limit.

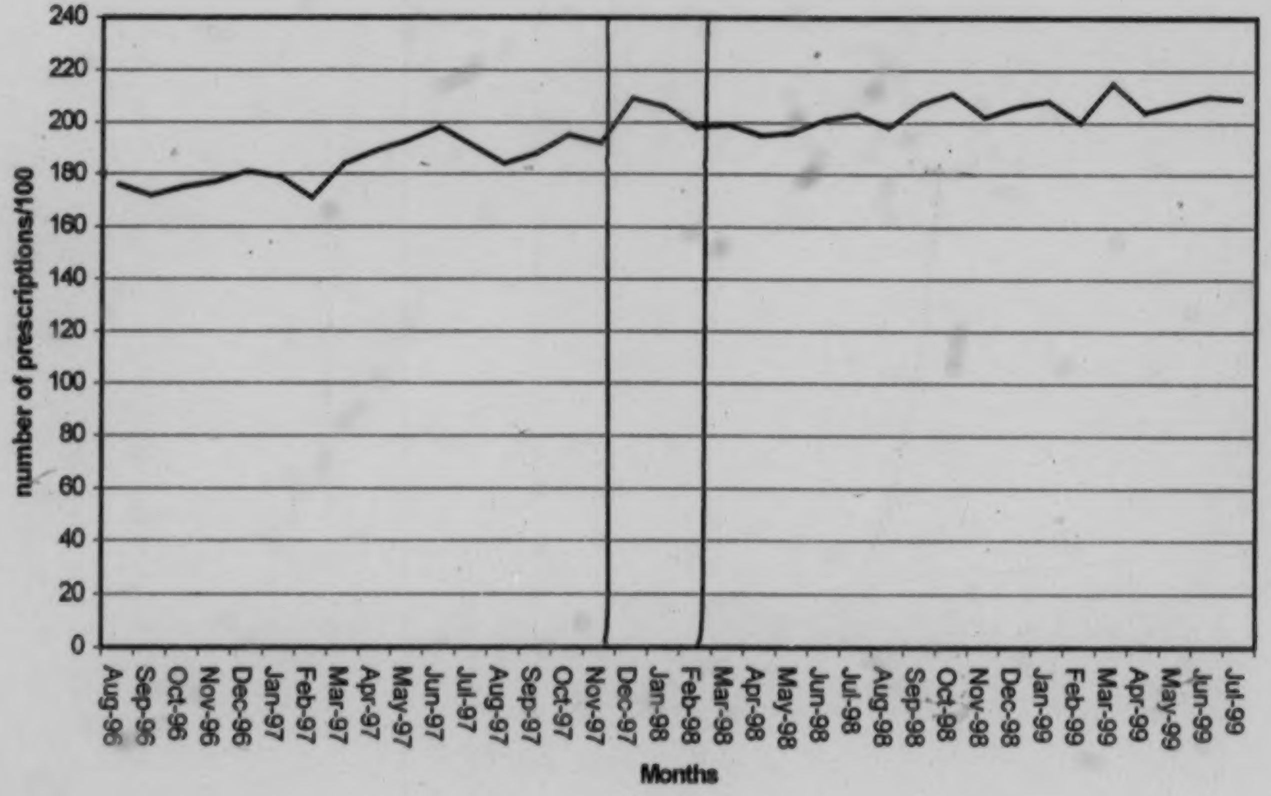


Figure 11: Costs of lithium (28:28:00) prescriptions per 100 recipients per month before and after the implementation of the $2.00 copayment and 30 days supply limits

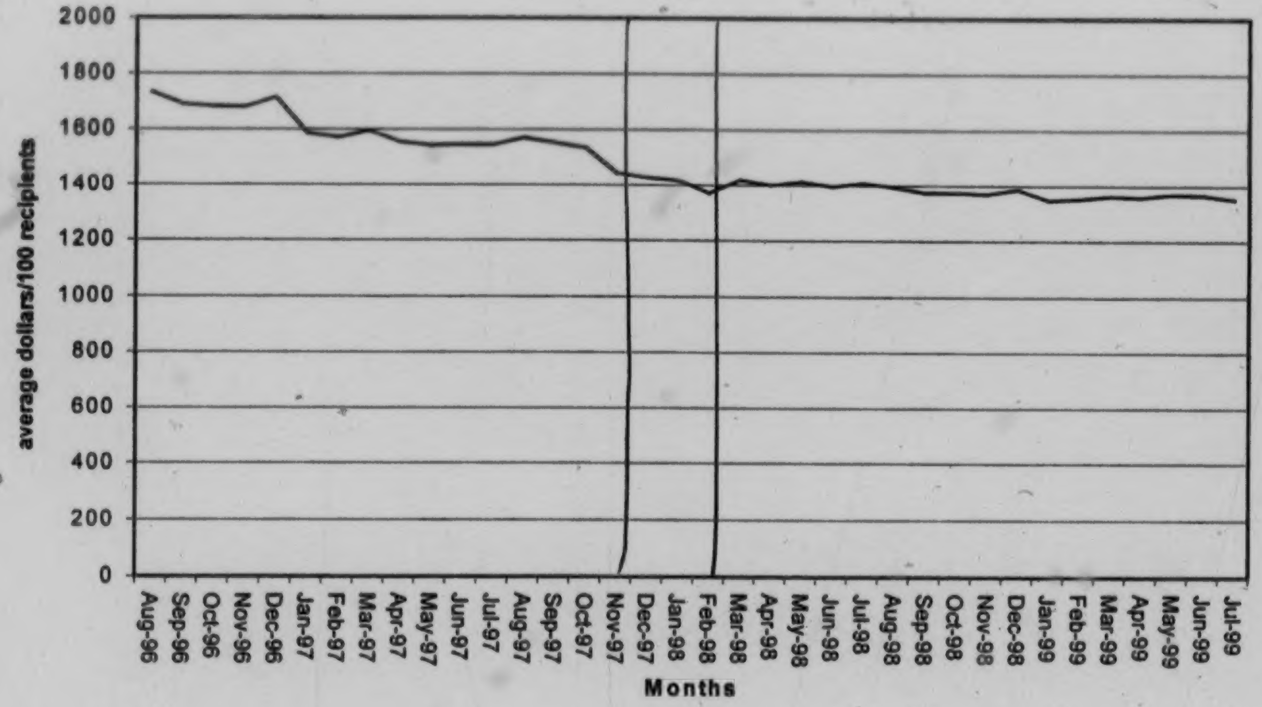
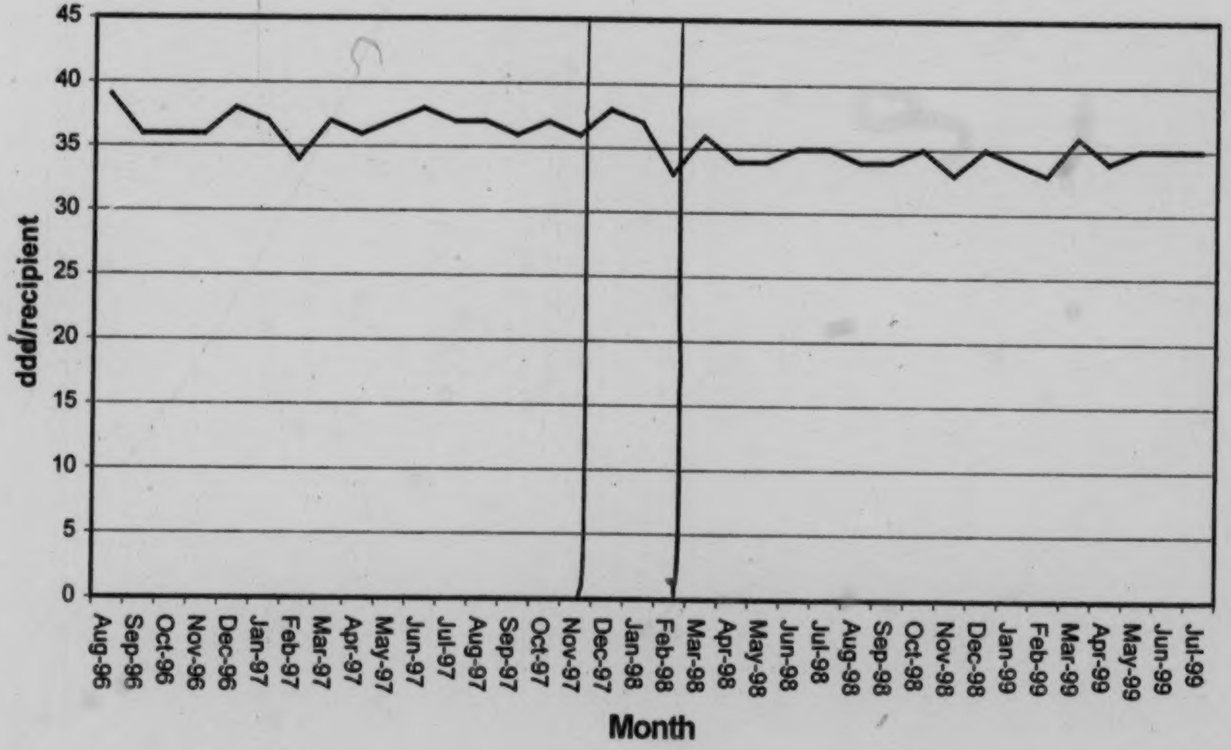


Figure 12: Number of defined daily doses per recipient per month for lithium (28:28:00) before and after the implementation of the $2.00 copayment and the 30 days supply limits



Therapeutic category 28:16:04- Selective Serotonin Re-uptake Inhibitors (SSRIs)

Prior to January 1998 the number of recipients having SSRIs numbered 7607 with a mean age of 44 years (range 18 to 83 years) and 39% male. From February 1998 onward recipients numbered 8552 with a mean age of 44 years (range 18 to 86 years) and 39% male.

Number of prescription per 100 recipients per month

The utilization of SSRIs was examined to ascertain the effect of the two policies. Data was collected from August 1996 to July 1999. Figure 13 describes the utilization of this class of medications using the number of prescriptions per 100 recipients. Visual inspection of Figure 13 suggests that utilization of this class of medications was increasing steadily until the introduction of the $2.00 co-payment in November 1997. It appears that prior to November a sharp decrease occurred followed by a sharp increase in month following. In February 1998, when the policy instituting a days supply limit of 30 days for this class of medications came into effect, there appeared to be a slight increase in utilization. By inspecting the graph, one would think that the introduction of both policies may have halted the increase in utilization that appeared to be taking place prior to November 1997. After the early months of 1998, it appears that utilization continues in a relatively constant trend until study's conclusion. Preliminary analysis of utilization supports this assertion. The mean number of prescriptions per 100 recipients per month was 170 prior to the $2.00 copayment being put in place. Between November 1, 1997 and January 31, 1998, the utilization increased to 180 prescriptions per 100 recipients per month. After the days supply limits were implemented, the utilization dropped to 176 per 100 recipients per month.

The following model described the impact of the $2.00 co-payment and the thirty days supply limits.

$Y_t=3.77Y_{t-1}-5.31Y_{t-2}+3.31Y_{t-3}-0.77Y_{t-4}+301.41-5.03X_{t1}-0.71X_{t1-1}-2.72X_{t2}+11.22X_{t2-1}+$

$-7.03X_{t2-2}+a_t+0.77a_{t-1}$

When the $2.00 co-payment policy was implemented, a decrease of 5.03 prescriptions per hundred recipients was realized (p=0.2790, 95%CI –14.29, 4.23 SE 4.56). When the 30 days supply limit was implemented, a non-significant (p=0.6267, 95%CI –13.95, 8.51, SE 5.53) decrease of 2.72 prescriptions per 100 recipients occurred. Though decreases in utilization did occur during the time periods the policy was implemented, time series data would suggest that the policy did not cause any significant decrease in utilization of SSRIs that could be attributed to both of the policies.

Dollars per 100 recipients per month

Figure 14 describes the utilization of selective serotonin re-uptake inhibitors in terms of dollars per 100 recipients per month. The graphical representation suggests that a decrease in expenditures on SSRIs was occurring prior to the $2.00 co-payment implementation and continued until the study's conclusion. A preliminary analysis of mean expenditures per 100 recipients per month supports this finding. The expenditures were $5,480.52 prior to November 1, 1997, $5,050.20 in the months after the copayment was implemented and $4,771.18 from February 1998 to July 1999.

The model was described by the following equation:

$$Y_t=3Y_{t-1}-3Y_{t-2}+Y_{t-3}-71.96-310.48X_{t1-1}+526.8X_{t2-3}-130X_{t2-4}+a_t$$

The mean decrease in dollars/100 recipients/month post-policy was $71.96. One month after the policy was implemented a significant decrease of $310.48 per 100 recipients occurred (p<0.0001, 95% CI –227.19, -393.69, SE 40.98). Three months after the days supply policy was implemented (April 1998) a significant increase of $526.80 per 100 recipients (p<0.0001, 95%CI 355.57, 698.03, SE 84.35) in expenditures occurred. Both Figure 14 and the time series model suggests that a decreasing trend in expenditures was occurring prior to the first policy being implemented. Once the $2.00 co-payment was in place, further decreases occurred until after the second policy was implemented. After this time, an increase occurred and a mean level of expenditures was maintained until the end of the observation period.

Defined daily doses per patient per month

Figure 15 describes the trend of ddd per recipient for selective serotonin re-uptake inhibitors. Visual inspection of the figure suggests that the utilization fluctuated around the time that the two policies were implemented. The mean level of utilization was 56 ddd per patient per month prior to the $2.00 copayment being implemented. It remained constant at this level after the copayment was in place and prior to the 30 days supply limits being enacted. From the time the 30 days supply limit was in place to the end of the study, the mean level of utilization was 52ddd/patient/month.

The time series model describing the impact of the policies is displayed below.

$$Y_t=3Y_{t-1}-3Y_{t-2}+Y_{t-3}+0.57-6.57X_{t1-2}+1.0X_{t2-2}-5.4X_{t2-3}+a_t$$

Two months after the policy was implemented, a significant decrease in utilization of 6.57 ddd per patient was realized (p<0.0001, 95% CI –8.32, -4.82, SE 0.86). Two months after the days supply limit policy was implemented, a non-significant increase of 1.0 defined daily doses per person was realized (p=0.53, 95%CI –2.17, 4.17, SE 1.56). This model suggests that the implementation of the policies may have caused a decrease in utilization.

Figure 13: Number of SSRI prescriptions (28:16:04) per 100 recipients per month before and after the $2.00 copayment and 30 days supply limits were implemented

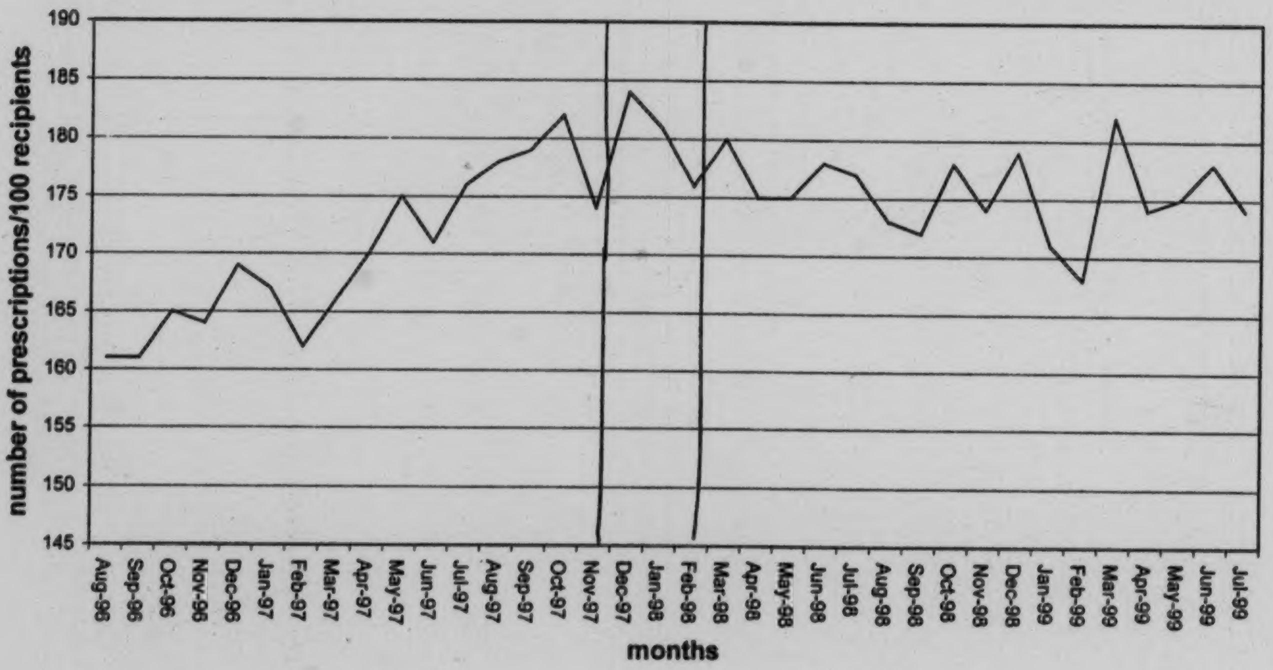


Figure 14: Expenditures on SSRIs (28:16:04) per 100 recipients per month before and after the implementation of the $2.00 co-payment and 30 day supply limit.

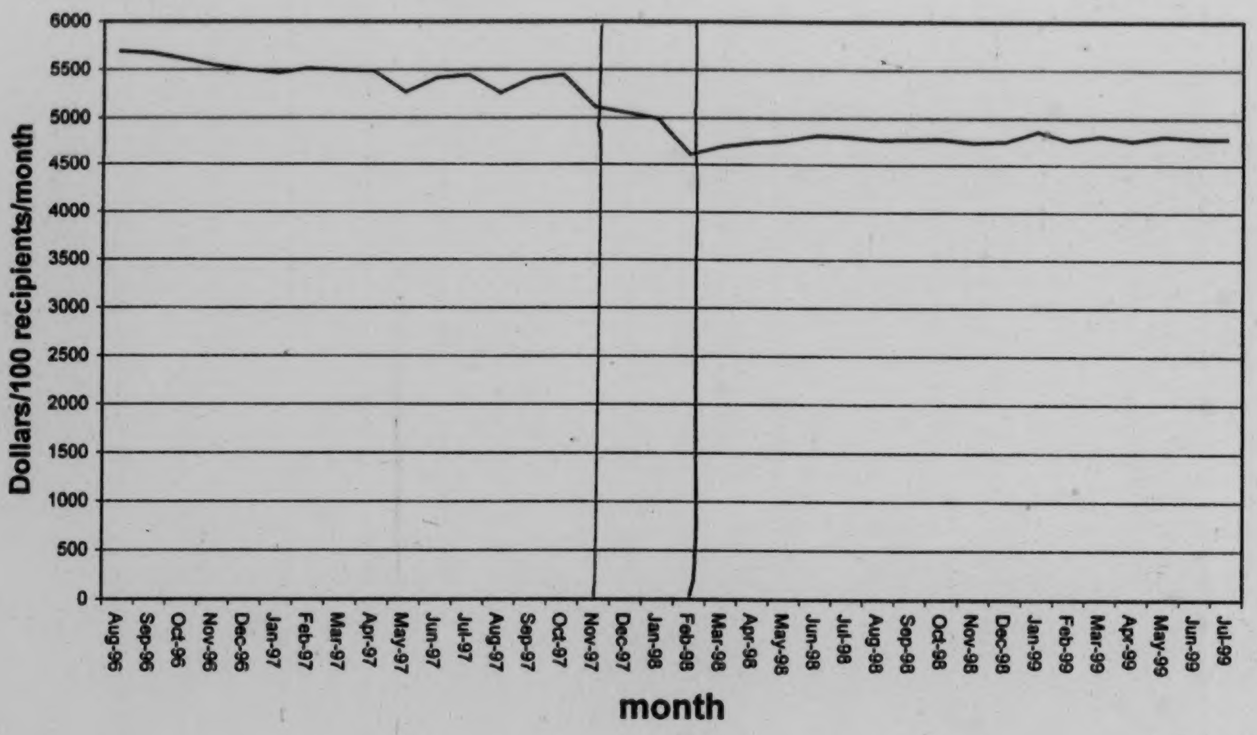
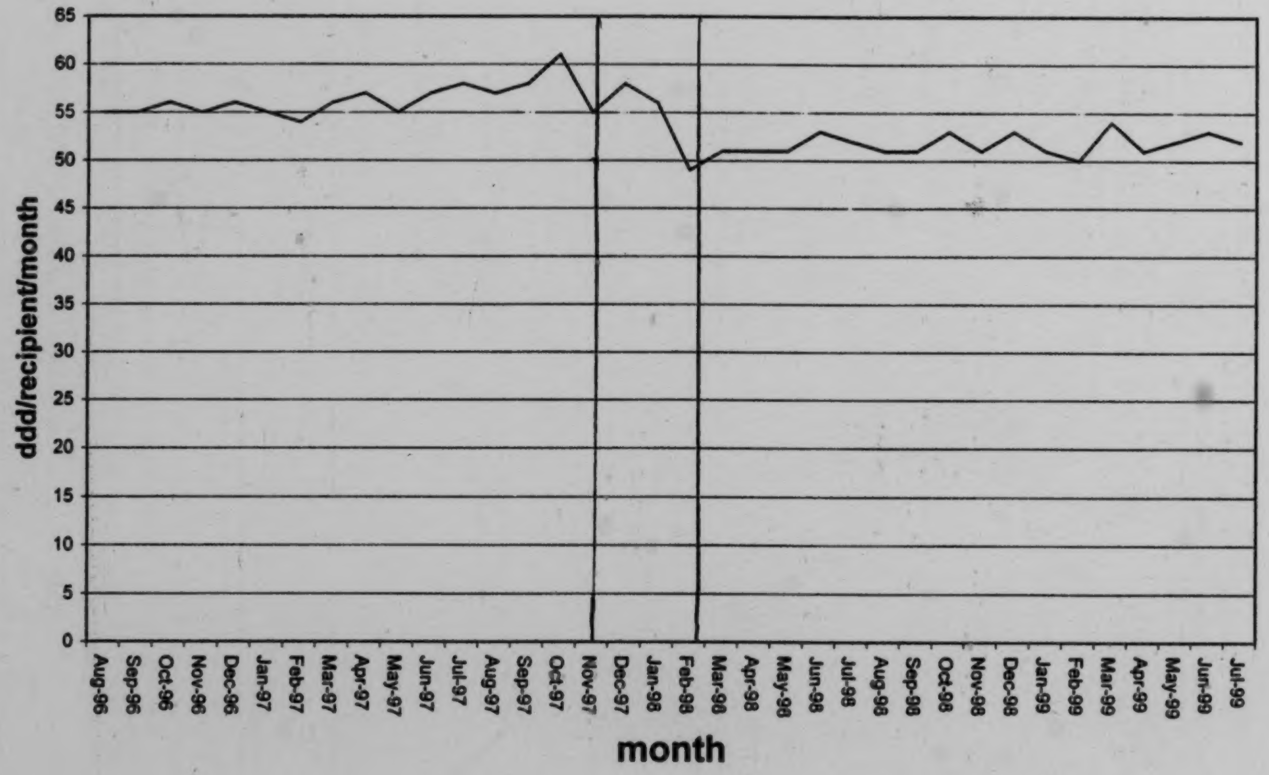


Figure 15: Number of defined daily doses per recipient for SSRIs (28:16:04) before and after the implementation of the $2.00 co-payment and 30 days supply limit.



Therapeutic category 28:16:08- Anti-psychotic medications

The number of AHRE recipients who utilized this class of medications prior to February 1998 numbered 7403. The mean age of recipients was 42 years (range 18 to 87 years) and 54.8% were male. From February 1998 onward recipients numbered 8110 with a mean age of 43 years (range 18 to 87 years) and 54.1% male.

Number of prescription per 100 recipients per month

Figure 16 is a graphical description of the utilization of anti-psychotic medications during the study time frame. Visual inspection of this figure suggests that anti-psychotic utilization was steadily climbing throughout the study period. The mean level of utilization was 219 prescriptions per 100 recipients per month prior to the copayment being implemented. At the time of the implementation of the copayment, utilization dropped, then immediately climbed again in December 1997. The level of utilization was 236 prescriptions pre 100 recipients per month between November 1, 1997 and January 31, 1998. When the 30-day supply limit was implemented in February 1998, the utilization appeared to increase once again. The mean utilization from February 1998 to the study's conclusion was 241 prescriptions per 100 recipients per month. Visual inspection of Figure 16 would suggest that both policies had little effect on the overall trend of utilization of anti-psychotics.

The following model described the impact of the $2.00 co-payment and the thirty days supply limits.

$$Y_t=3Y_{t-1}-3Y_{t-2}+Y_{t-3}+5.14-6.14X_{t1-2}+3.65X_{t2-1}+a_t$$

There were an average number of 5.14 new prescriptions per 100 recipients per month after the policy was implemented. Two months after the $2.00 co-payment policy was implemented, a statistically non-significant decrease of 6.14 prescriptions per hundred recipients was occurred (p=0.3133, 95%CI –18.30, 6.02, SE 5.99). The time series model also suggests that Policy 2 had little impact on the utilization of anti-psychotics. One month after the 30 days supply limit was implemented in February 1998, a non-significant (p=0.5427, 95%CI –8.37, 15.67, SE 5.92) increase of 3.65 prescriptions per 100 recipients occurred.

Dollars per 100 recipients per month

Figure 17 describes the AHRE expenditures on anti-psychotic medications for the duration of the study. It is evident from the graph that expenditures on this class of medications climbed steadily throughout the time period and that both policies had little effect in decreasing expenditures. The level of expenditure rose from $5,087.05 per 100 recipients per month to $6,430.30 per 100 recipients per month and again to $6,881.60 in the timer period prior to November 1, 1997, between November 1, 1997 and January 31, 1998, and from February 1, 1998 onward, respectively.

The time series model supports the above assertion. The model was described by the following equation:

$$Y_t=3Y_{t-1}-3Y_{t-2}+Y_{t-3}+395.14-117.68X_{t1}-167.48X_{t2-2}+a_t$$

The mean increase in dollars/100 recipients/month post-policy was $395.14/100 patients/month. In the month the copayment policy was implemented a non-significant decrease of $117.68 per 100 recipients occurred (p=0.4031, 95% CI –399.34, 163.98, SE 138.75). The implementation of the 30 days supply limit on anti-psychotic medications did not have any significant impact on expenditures. The model suggests that two months after the second policy was implemented, a non-significant decrease of $167.48 per 100 recipients per month occurred (p=0.2195, 95% CI –438.55, 103.59, SE 133.55).

Defined daily doses per patient per month

Figure 18 describes the trend of ddd per recipient for anti-psychotic medications. A review of the graph suggests that a steady decreasing trend in defined daily doses per patient per month occurred throughout the study time period. Visual inspection of the graph alone would suggest that despite the fact that some fluctuation in utilization had occurred when the policies were implemented, the policies did not have an effect on the trend in utilization. The mean utilization prior to November 1997 was 48 ddd per recipient per month. In the time between the implementation of the $2.00 copayment and 30 days supply limits, the utilization was 47 ddd per recipient per month and from February 1, 1998 onward the utilization was 43 ddd per recipient per month.

The model is described below:

$$Y_t=3Y_{t-1}-3Y_{t-2}+Y_{t-3}-0.43-2.24X_{t1-2}+2.10X_{t2-2}+a_t$$

Two months after the copayment policy was implemented, a significant decreases of 2.24 ddd per patient was realized (p=0.0244, 95% CI –4.15, -0.33, SE 0.94). Two months after the days supply limits were imposed, a significant increase of 2.10 defined daily doses per person was realized (p=0.0316, 95% CI 0.21, 3.99, SE 0.93). Though a significant decrease did occur after the copayment policy was implemented, a significant increase of nearly the same amount occurred two months after the days supply limits were imposed. Given this fluctuation surrounding the policies' implementation, it is difficult to conclude that the policies are responsible for the decreasing trend.

Figure 16: Number of anti-psychotic prescriptions (28:16:08) per 100 recipients per month before and after the implementation of the $2.00 co-payment and 30 days supply limit.

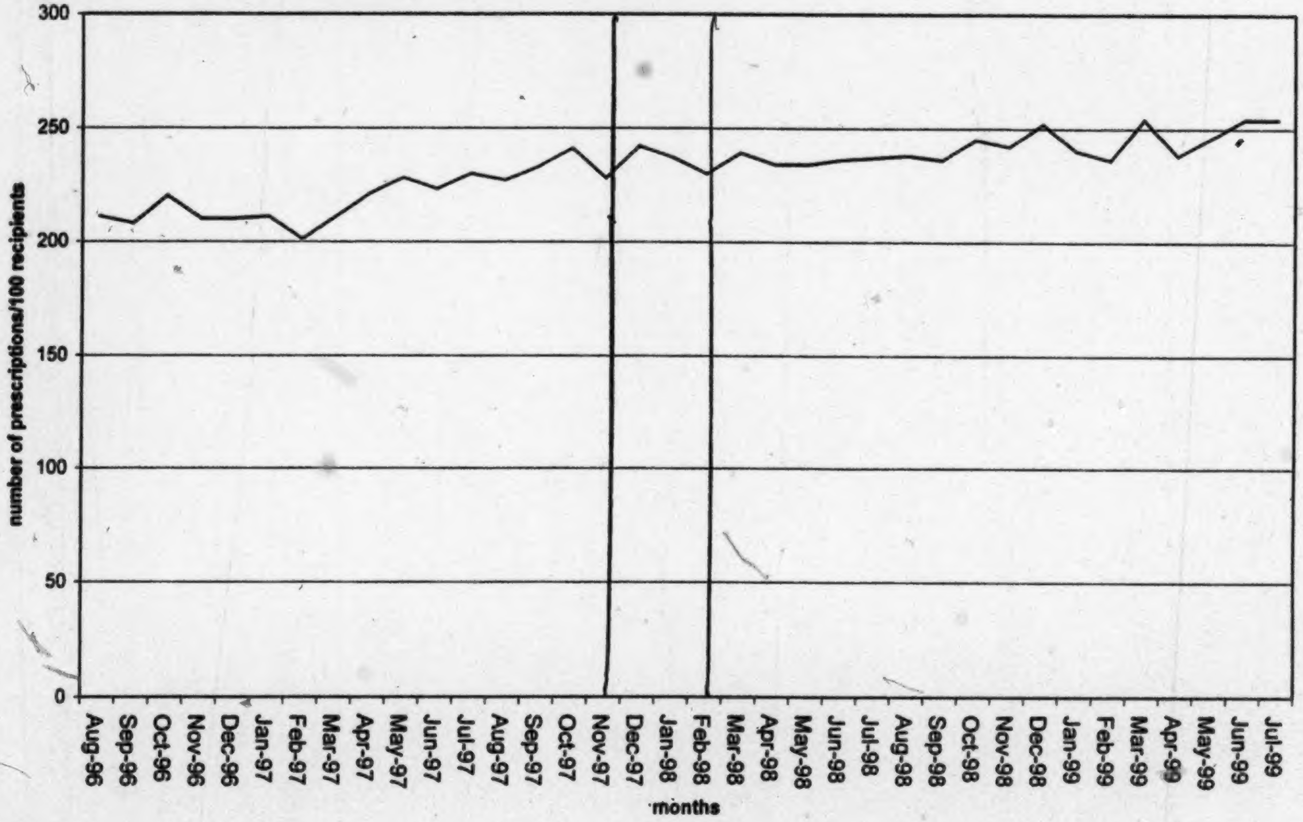


Figure 17: Expenditures on anti-psychotics (28:16:08) incurred per 100 recipients per month before and after the implementation of the $2.00 co-payment and 30 day supply limit.

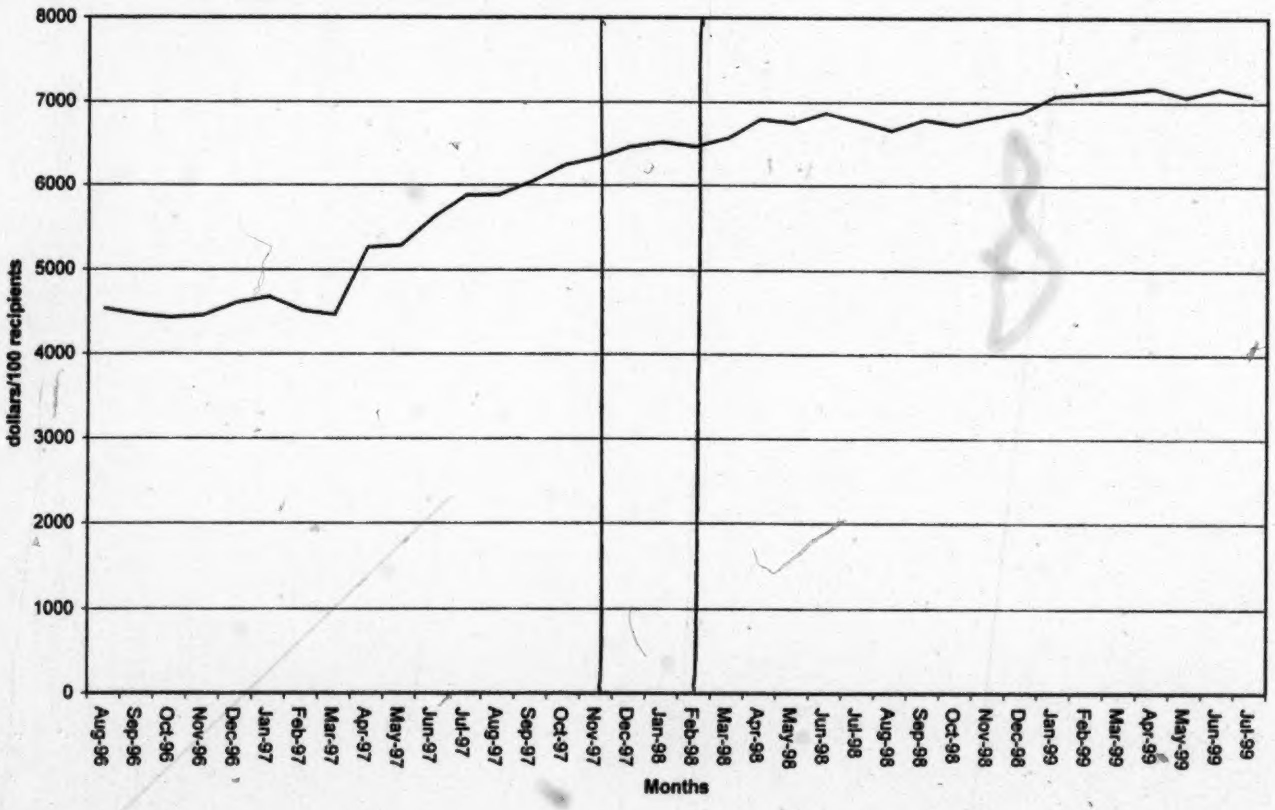
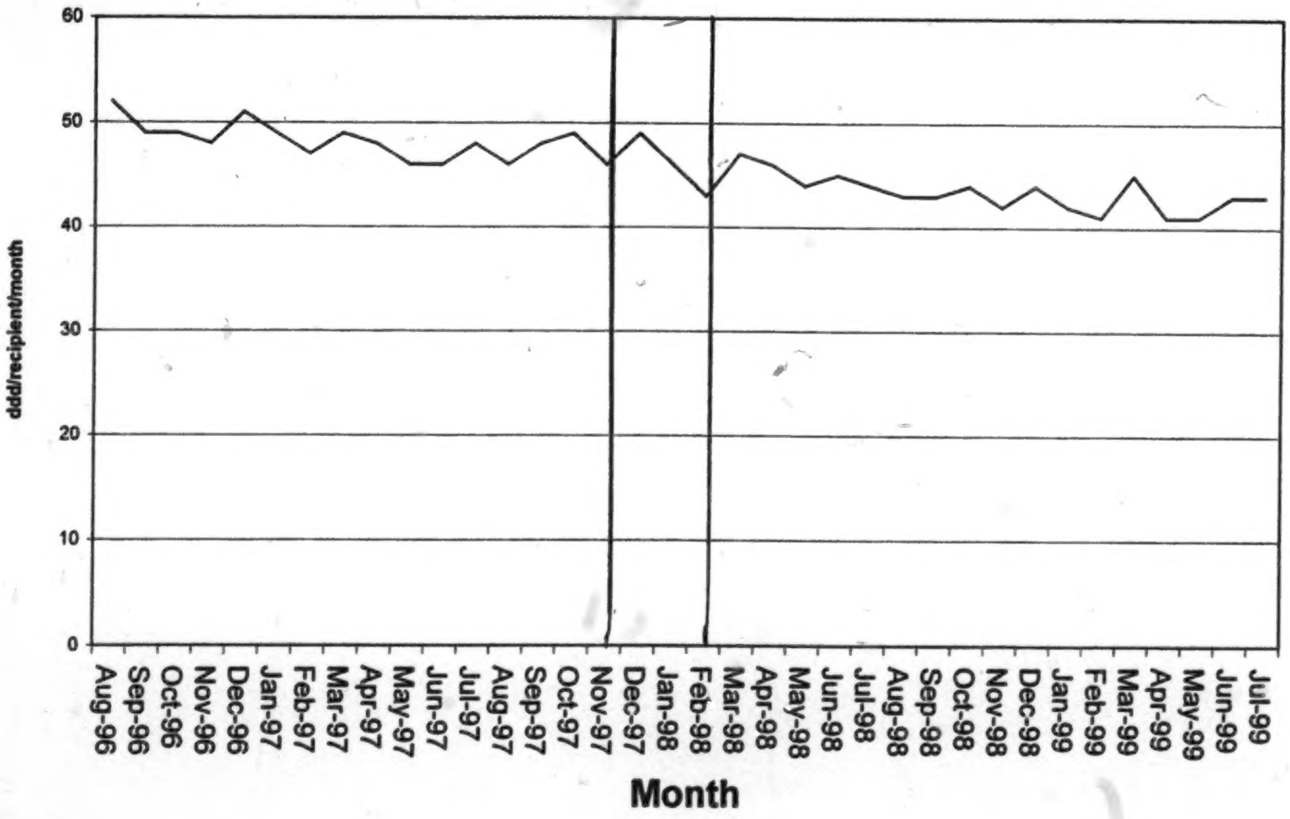


Figure 18: Number of defined daily doses per recipient per month for anti-psychotic medications (28:16:08) before and after the implementation of the $2.00 co-payment and 30 days supply limit.



b

Summary

Analysis of drug claim data suggested that the policies had a variable impact on drug utilization. Table 10 summarizes the findings of the time series analysis. The policies may have had little impact on anti-manic agents. There was an increasing trend in SSRI use but significant decreases in expenditures were experienced during that time. The policy appeared to affect the measure of ddd per recipient per month. Finally, in the anti-psychotic category, the $2.00 copayment and days supply policies did not have a significant impact on utilization and expenditures.

Table 10: The effect of the $2.00 copayment and days supply limitation

Therapeutic Category	Indicator	Time series analysis findings		Overall trend
		Policy 1	Policy 2	
28:28:00 Anti-manic agents	Number of prescriptions/100 recipients/month	20.28 (1 month post-policy) p<0.001 95%CI 13.09, 28.55		increasing
	Dollars/100 recipients/month	-$73.97(post-policy) p=0.0008 95%CI –114.12, -33.82	$103.74 (1 months post policy) p<0.0001 95%CI 65.09, 142.39	decreasing
	DDD/recipient/month	-1.67 (2 months post-policy) p=0.0751 95%CI –3.5, 0.16	-1.33 (1 month post-policy) p=0.4225 95%CI –4.66, 2	decreasing
28:16:04 Psychotherapeutic agents (SSRIs)	Number of prescriptions/100 recipients/month	-5.03 (post policy) p=0.2790 95% CI –14.09, 4.23	-2.72 (post=policy) p=0.6267 95% CI - 13.95, 8.51	increasing
	Dollars/100 recipients/month	-$310.48 (1month post policy) p<0.0001 95%CI –227.19, -393.69	$526.80 (3 month post-policy) p<0.0001 95%CI 355.57, 698.03	decreasing
	DDD/recipient/month	-6.57 (2 month post-policy) p<0.0001 95%CI –4.82, -8.32	1.00 (2 months post-policy) p=0.53 95%CI –2.17, 4.17	decreased and then constant
28:16:08 Psychotherapeutic Agents (Anti-psychotics)	Number of prescriptions/100 recipients/month	-6.14 (2 month post-policy) p=0.3133 95%CI –18.30, 6.02	3.65 (1 months post-policy) p=0.5427 95%CI –8.37, 15.67	increasing
	Dollars/100 recipients/month	-$117.68 (post-policy) p=0.4031 95%CI –399.34, 163.98	133.55 (2 month post-policy) p=0.2195 95%CI –438.55, 103.59	increasing
	DDD/recipient/month	-2.24 (2 month post-policy) p=0.0244 95%CI –4.15, -0.33	2.10 (2 months post policy) p=0.0316 95%CI 0.21, 3.99	decreasing

CHAPTER 5

DISCUSSION

Three methodologies were used to examine the impact of policy changes in the Alberta Human Resources and Employment prescription drug program. The first phase of the project involved focus groups with various stakeholders to gain an understanding about the process of policy implementation in the community. In addition, stakeholder opinions were sought about the possible impact the policy may have had. The second phase of the study involved the use of a survey of a random sample of practicing Alberta community pharmacists to generate information about their opinions of the policy as well as to understand how pharmacists implemented the policy in their dispensaries. Finally, time series analysis of drug claim data was completed to ascertain whether the policy had any impact on drug utilization of select medication classes.

The following section discusses the results of the policy evaluation conducted to evaluate the AHRE prescription drug policy changes using Pal's policy evaluation framework. As this policy evaluation used a variety of methodologies, the discussion will begin with the introduction of the concept of triangulation. Limitations of the study will be reviewed and finally, policy implications and directions for future research are presented.

Triangulation

The concept of triangulation was introduced by Campbell and Fiske (1959) who argued for the need to measure a single concept in a variety of different ways so that the extent to which different measures converged could be ascertained (Campbell & Fiske, 1959; Jick, 1979; Nolan & Behi, 1995). In this sense, triangulation emerged from the quantitative research paradigm (Bazeley, 1999). Approximately ten years later, Denzin applied this approach to qualitative research in the social sciences (Denzin, 1970).

There are two main purposes of triangulation. The first is to achieve confirmability, which may be defined as different methods applied to the same area of study so that the results of one set of measures may confirm those of another. Such an approach is similar to the Campbell and Fiske's original notion of triangulation (Campbell & Fiske, 1959). The second is to achieve completeness, which asserts that different methods are more suited to discover different aspects of the issue under study. To achieve completeness, different methods are hypothesized to provide insights that might be missed had only one methodology been used. Both approaches to triangulation are complementary (Knafl & Breitmayer, 1991).

Historically, triangulation has involved the use of different methodologies within either a quantitative or qualitative research paradigm with little mixing of the paradigms. Increasingly, triangulation has been completed by utilizing both qualitative and quantitative methodologies in combination with each other (Morse, 1991). It has been suggested that the use of both qualitative and quantitative methods are complementary and provide a greater understanding of both process and outcome. The use of triangulation is particularly applicable to the discipline of policy analysis as triangulation uses complementary methods that provide insight into process and outcome (Bazeley, 1999) that are at the core of policy evaluation (Brewer & deLeon, 1983; Hofferbert, 1985; Pal, 1997).

There are several advantages to using both qualitative and quantitative methods. Reasons include 1) greater sensitivity to variations in data, 2) ability to ask new questions, 3) examination of qualitative detail in the context of broader quantitative picture, 4) a single methodology used alone may be incomplete depending on the issue examined and the real life constraints on data that are available and 5) causality may be modeled in different ways (Bazeley, 1999).

Denzin and Lincoln (1994) outlined different types of triangulation that may occur including, 1) method, 2) data, 3) investigator and, 4) theoretical (Denzin & Lincoln, 1994). In methodological triangulation, different methodologies are used to address the same issue. Jick asserts that the use of different methodologies may serve to improve the completeness of a study as different methodologies may raise issues that were previously unknown (Jick, 1979). Data triangulation is based on the use of different sources of data for the same issue under study. An example of this would be collection of data from different individuals about the same topic. Investigator triangulation is the use of different researchers investigating the same topic. Finally, theoretical triangulation is when different theoretical models are used to examine the same subject (Denzin & Lincoln, 1994).

This study used method and data triangulation to examine the process of policy implementation and the impact of the policy. The use of data triangulation was implemented when data from various focus groups were compared to generate an understanding of how the policy was implemented and how it affected the stakeholders. For example, triangulation of focus group data allowed for an in-depth analysis of the process of policy implementation from the perspective of pharmacists, AHRE clients and health care agency and community representatives. Methodological triangulation was exemplified by the use of focus group techniques, a self-administered mail survey and time series analysis of drug claim data to complete a policy evaluation of AHRE prescription drug policy changes. Focus group data served not only to provide opinion about the policy and assist in the development of survey items, but it also provided context and confirmation for answers given in the survey. For example, AHRE clients suggested that there were certain types of pharmacies that were likely to violate the policy. Survey findings concurred with the focus group results. Methodological triangulation also provided information on shortcomings in the process of policy implementation that may, in turn, have affected the impact the policy had on drug utilization.

Despite positive aspects of using triangulation in research, difficulties may emerge. These difficulties generally arise in combining both qualitative and quantitative methodologies within the framework of one study. The first difficulty is the refusal of researchers to accept the validity of other methods (Bryman, 1988). In answer to this issue, Janesick has called for elasticity of design to ensure that both qualitative and quantitative methods receive equal consideration throughout the research process (Janesick, 1994). The second issue is the emergence of definitional drift that is defined as the blending of multiple methodologies at the expense of their distinct theoretical approaches (Sandelowski, 1995). An example of definitional drift may be using a random sample of respondents for a focus group rather than purposeful sampling, which would violate the theoretical assumptions of qualitative research. Morse (1991) has suggested that it is possible to avoid this downfall by ensuring that the methods remain separate, yet complimentary. She asserts that it is vital to ensure that the theoretical underpinnings of each chosen method remain intact so as not to compromise the method

(Morse, 1991). The final issue emerges when one method, often the qualitative one, is viewed as less important or offering less in terms of the information it provides in the results (Mitchell, 1986; Morse, 1991). Ensuring that each research paradigm is viewed as contributing equally to insight generated by the research may be accomplished by viewing each methodology as fitting into a puzzle (Morse, 1991).

In summary, triangulation may be used to achieve confirmability and completeness. Doing so often requires the use of both qualitative and quantitative methodologies to provide insight into process and outcome. The following section will discuss the implications of findings using the policy analysis framework outlined by Pal. Results of all three methodologies will be triangulated throughout this section to illustrate how methodologies provide both confirmability and completeness of findings.

Process evaluation

Data and methodological triangulation ensured that the findings of the process evaluations were confirmable and complete (Knafl & Breitmayer, 1991). Data triangulation was operationalized by comparing the focus group findings from each of the stakeholder groups. Similarities and differences between the stakeholders were sought in an effort to confirm or disprove the opinions of each group. For example, AHRE clients suggested that some pharmacists waived the copayment. Data from agency and pharmacists' focus groups confirmed this finding. Completeness was also assured by this process when each group provided different perspectives about the policy.

Methodological triangulation achieved confirmability and completeness in a similar manner. This process involved the comparison of survey findings with that of the focus groups. Triangulation of focus group and survey results provided insight into what the various stakeholders believed to be occurring in the process of policy implementation that, in turn would have an effect on the impact of the policy. Several themes emerged that related directly to the process of policy implementation. First, all of the groups interviewed suggested that the policy may have been more effectively disseminated by AHRE. Second, pharmacists did evade the policy and specific pharmacist and pharmacy characteristics were identified that appeared to predispose them to policy evasion. Third, pharmacists were placed in an awkward position in having to choose to violate the policy or provide care to patients. Finally, beneficiaries possessed several methods of policy evasion.

Focus group results suggested that improvement of dissemination techniques and ensuring that AHRE clients were aware of the policy would have alleviated some of the implementation issues that had arisen. Individuals in the pharmacist focus group were frustrated that they were obligated to be the 'bad guy' and request the copayment, particularly when AHRE clients appeared to not understand what was required of them.

Pharmacists suggested that they were required to repeatedly advise patients of their responsibility for the co-payment on the first three prescriptions each month. They suggested that perhaps patients were not notified appropriately, may not have been literate enough to understand documentation included in monthly allowance cheques or that notification on cheques was not understandable to the clients or not obvious enough. A review of Alberta Government news releases indicated that the first official announcement of the implementation of a $2.00 copayment was on July 25, 1997(Government of Alberta, 1997). However, according to an internal AHRE memo dated October 17, 1997, a communication was scheduled to be sent with the clients' monthly support cheques advising them that a $2.00 copayment would be required for the first three prescriptions each month effective November 1, 1997. Given the timing of this memo, it does not appear that clients were provided with official notification of the policy change well in advance of the policy being implemented. Focus group and survey data support this assertion as results indicate that clients were not aware of the policy until after it was implemented (Alberta Human Resources and Employment Directive, 1997).

The AHRE client focus groups confirmed that advertisement about the policy was not optimal, as the majority of clients stated they were surprised the first time that they were asked to pay the co-payment. In addition, the AHRE clients suggested they were not aware of all of the changes made to the prescription drug program. For example, only a few clients interviewed were aware that five dollars per month was added to their monthly allowance cheques to partially compensate for prescription medications.

There does not appear to be other Canadian literature evaluating beneficiaries' knowledge about drug policy changes. However, a study that explored low income Edmontonians' views about access to medications serves to support the assertion that AHRE clients possess a lack of understanding about health care policies affecting them. Williamson reported that 49% of AHRE clients did not obtain their prescription medications because they could not afford them. This study was conducted prior to AHRE drug policy changes being implemented therefore all prescriptions were free of charge to AHRE beneficiaries (Williamson & Fast, 1998). If AHRE beneficiaries possessed little knowledge about their current copayment situation, they would likely not be aware of changes to it. These findings are not unique to the Canadian population, as it appears that some drug policy changes in the U.S. Medicaid population have also suffered from poor dissemination. Hopkins et al., surveyed beneficiaries about their knowledge of changes to California Medicaid policy in 1972 and found that 40% did not understand the policy (Hopkins et al., 1975a).

The focus group discussion with representatives from health care and community agencies echoed the suggestion for improved dissemination and provided context for why some AHRE clients may not have been aware of the policy. First, the agency representatives reiterated that their clients were not aware of the intricacies of the policy. It was also suggested that news of the prescription drug policy changes came almost simultaneously with notification that AHRE clients would be required to have bank accounts to facilitate direct deposit of their monthly allowance cheques. A representative who worked with particularly vulnerable clients living in the inner city suggested that the change to bank accounts took priority over the change in prescription drug plans as her clients were apprehensive about having to set up an account. The requirement for bank accounts distracted clients from the reality that they would be required to pay for prescriptions. It is important to note that this finding may be specific to more vulnerable segments of the AHRE populations than those who may function more effectively within society. Nonetheless, additional social services policy changes at the same time that drug policy changes occurred may have precluded clients from having a good understanding of the policy.

The survey methodology provided information on policy dissemination. The dissemination of the policy was partially captured by the constructs labeled policy administration and pharmacy administration. Policy administration captured the implementation of the policy and included dissemination. While pharmacy administration did not explicitly deal with the dissemination of the policy, it did reflect how difficult pharmacists believed the policy was to administer in their pharmacies. For example, items within the pharmacy administration construct related to explaining the policy to AHRE clients. The frequency with which pharmacists were forced to explain the policy also reflects the policy's poor dissemination.

Second, the survey provided data indicating that pharmacists with specific characteristics may be prone to policy evasion. Focus group results refer to policy evasion as the evasion or waiving of the co-payment. When focus group data was triangulated, interesting findings were identified. First, pharmacists reported that select stores had made it a policy to waive the fee. It was suggested that policy evasion was an initiative to attract additional social services clientele. Though none of the pharmacists in the focus group identified their stores as doing so, some pharmacists admitted to waiving the fee occasionally. Reasons for doing so included, for example, frustration with having to explain the policy or feeling sorry for the patient. Pharmacists viewed stores who made it a policy to waive the fee negatively and believed that all stores should be policed to ensure that they were compliant with the policy.

In contrast, agency representatives and clients viewed pharmacists who waived the fee to be admirable. In fact, there seemed to be an unspoken referral program to stores that were less likely to charge the fee. Further, clients themselves had ideas about types of pharmacies that would be more likely to waive the fee than others and were most likely to visit the types believed to waive it. Specifically, large chain stores were identified as being unlikely to waive the fee whereas small, independent pharmacies were identified as more likely to do so. This finding was substantiated by results from the pharmacist survey that showed independent pharmacies were statistically significantly more likely to be noncompliant with the policy than chain, retail or grocery store pharmacies. The survey instrument uses the construct labeled "policy compliance" to describe the actions of pharmacists that may not comply with the policy. Therefore, this construct contains items referring to waiving the copayment and violating days supply restrictions. However, it is important to note that five of the seven items in this construct focused on waiving the copayment.

The survey findings provided further insight into what types of pharmacists may be more likely to be noncompliant with the policy. One question that asked whether it was a store policy to waive the fee revealed that only three percent of stores did so. A study conducted by Fahlman et al. (2001) that specifically asked about store policy on copayment enforcement found that 37% of pharmacies did not have policies to enforce copayments. The researchers found that pharmacists practicing in stores without specific copayment policies were more likely to waive the fee than those who worked in stores with policies that enforced copayment collection.

Pharmacists were also asked how often they personally were noncompliant with the policy. It seemed that the more positive a pharmacist was toward the policy's administration in the pharmacy, the less likely they were to be noncompliant. For example, younger pharmacists fell into this category. Generally, the more positive a pharmacist was about the administration of the policy in the pharmacy, the more likely they were to have negative perceptions of social services clients. Beliefs that clients may be undeserving of assistance, irresponsible or simply "using" the social services system may have precluded these pharmacists from being noncompliant.

An interesting finding was that the higher the volume of AHRE clients within a pharmacy, the more positive pharmacists were towards the administration of the policy and the more negative their perceptions of clients. However, pharmacists in such stores were more likely to be noncompliant with the policy than stores with a lower volume of AHRE clients. Two reasons may be attributed to this finding. First, stores with a high volume of AHRE clients may have pharmacists who agree with the policy and are somewhat negative toward clients because of their increased interactions with them. Yet, these pharmacists want to maintain their revenue from AHRE clients' prescriptions so they are noncompliant with the policy. Second, perhaps the reason that stores have a high volume of clientele is because they have been identified by clients as being noncompliant with the policy. At the time of the survey the policy had been in place for over two years. Enough time had passed to ensure that clients were aware of which stores may be noncompliant with the policy. The fact that these stores have a higher clientele may be an artifact of the store's non-compliance as opposed to the pharmacists' personal choice to do so. A study completed in the U.S. that asked pharmacy owners and managers about implementation of cost-sharing policy found that pharmacies with a high volume of social services clientele were more likely to waive the copayment (Fahlman, Stuart, & Zacker, 2001).

The third finding of significance was that pharmacists were placed in an awkward position of choosing to violate the policy to provide individuals who could not afford their medications with prescriptions. It is interesting to note that despite the fact that pharmacists are contractually required to charge the copayment, a number of pharmacists admit to not doing so. As discussed previously, there were several pharmacist characteristics that were linked this to this behavior. Ensuring that patients always pay the copayment may place pharmacists in an ethical dilemma if they believe that the patient is unable to afford it. Despite the fact that patients are provided an additional sum of money on their monthly allowance cheques to assist them in purchasing prescription drugs, pharmacists did identify that some individuals would choose to allot these monies to other household needs. This appeared to be of particular concern when pharmacists believed that patients were "good" beneficiaries and were being unfairly punished by the policy. It appears that pharmacists practicing in Alberta will continue to experience this quandary when faced with patients who appear to not be able to afford their medications. In contrast, pharmacists practicing in the U.S. are provided means in which to waive the copayment if they feel it is justified - U.S. federal law stipulates that providers must not collect copayments if they believe that doing so would cause them to deny their necessary services to the client (Fahlman et al., 2001) Though U.S. pharmacists are provided with more freedom that their Alberta counterparts, they remain in the position of having to assess whether a patient is truly in need and unable to purchase a medication because of the copayment. In addition, they are forced to make the choice to waive the copayment for such clients and be penalized financially (Fahlman et al., 2001).

Finally, beneficiaries possessed several methods of avoiding the copayment. Pharmacists and clients reported methods that could be used to evade the policy in focus groups. Interestingly, both pharmacist and client focus groups suggested that the "good people" were responsible and paid the copayment, whereas those who were drug abusers or used medications inappropriately evaded the policy. Perhaps the methodology that provided the greatest insight into this finding were the focus groups. Analysis of pharmacist focus group data provided insight into different methods of policy evasion committed by beneficiaries that they had observed. These methods of evasion ranged from influencing pharmacists by making them feel guilty for charging the copayment to leaving the first three prescriptions that they filled each month at one pharmacy and so that the remainder of the prescriptions they filled at another pharmacy would be received free of charge. Focus groups with AHRE clients supported that clients used a variety of means to evade the policy. Some reasons, such as lack of money, were considered valid excuses for policy evasion. However, they also noted that some individuals "cheated" the system and received extra medications for addictions or subsequent selling of prescription drugs. Perhaps, a response to such methods of policy evasion may be the implementation of tiered copayment systems that would possess higher copayments for medications deemed as nonessential and little or no copayment for medications deemed as essential (Motherall, 1998).

Impact Evaluation

The time series data provided insight into the impact the policy had on drug utilization and expenditures. Again, the use of methodological triangulation played an integral role in achieving confirmability and completeness of the findings. Findings from the process evaluation component of this study found that the policy was implemented in a variable manner and stakeholders believed that the policy may not have affected utilization.

The findings from the time series analysis appear to support these findings. The time series analysis dealt only with medications that could be termed essential or necessary for patients to stabilize a chronic condition. Time series analysis of drug claims data used to evaluate the $2.00 copayment policy implemented in November 1997 examined the use of sulfonylureas, miscellaneous antidiabetic agents and ACE inhibitors.

Analysis of sulfonylureas data suggests that significant decreases in the number of prescriptions per 100 recipients occurred two months after the policy was implemented. However, due to the increasing trend in the series, it appears that the effect of the policy was not sustained. An evaluation of the change in DDD/recipient/month suggested that a significant decrease occurred three months post policy. Again, the trend in the series would suggest the $2.00 copayment had little effect.

Analysis of miscellaneous antidiabetic agents showed that there were no significant effects on the number of prescriptions or the AHRE expenditures after the implementation of the policy. A significant decrease in defined daily doses occurred post policy however, an increasing trend was seen over the course of the study. The increasing trend of the utilization of these medications may be explained by changes in the clinical practice guidelines for the management of diabetes as well as the results from large trials studying the effects of the treatment of diabetes. In October 1998, the Canadian Medical Association released clinical practice guidelines for the management of diabetes (Meltzer, et al., 1998). That same year the UK Prospective Diabetes Study (UKPDS) Group released the results of their large scale trial examining the treatment and long-term complications of blood glucose control. Subsequently, the Canadian Diabetes Association released recommendations that addressed the additional information provided by the UKPDS trial. These revised guidelines advocated the intensive management of blood glucose, blood pressure and blood lipids. In addition, the revised guidelines advocated the use of metformin, which is classified as a miscellaneous anti-diabetic medication, as an initial therapy for obese patients with Type 2 diabetes (Gerstein et al., 1998).

The final category of drug examined to determine the impact of the copayment policy was the ACE inhibitors. The number of prescriptions per 100 recipients/month experienced a significant increase in the time period surrounding the policy's introduction while expenditures showed a decrease. The DDD/recipient/month showed a significant decrease post policy, however, the series fluctuated at a slightly higher level post-policy. Though examination of additions to the AHRE formulary did not reveal any additions of ACE inhibitors that appear to have contributed to the increase in dosage, changes in the approach to treating hypertension may have played a role. In fact, the clinical practice guidelines for diabetes may have had an impact in this clinical arena also, as recommendations for tight blood pressure control to ameliorate the long term complications of diabetes were advocated (UKPDS, 1998).

In general, the introduction of the $2.00 copayment did not cause significant and long term effects on the numbers of prescriptions or expenditures by AHRE. Changes in the management of Type 2 diabetes may be a plausible explanation for why the use of the antidiabetic agents increased during the study (Meltzer, et al., 1998). Again, with regard to ACE inhibitors, an increase in DDD per patient may also be attributed to changes in the management of hypertension in patients both with and without diabetes. Finally, increasing trends in the prevalence of diabetes and hypertension in Alberta may also have played a role in the lack of impact seen in expenditures on these classes of prescription drugs . An increase in disease prevalence would indicate that more patients are being diagnosed with hypertension and diabetes and, in turn, likely being treated with prescription drugs. Hence, this increase in prevalence may relate to the increase in utilization. Regardless, it appears that the introduction of this policy did not negatively affect the utilization of these medication classes.

Time series analysis of anti-manic agents, SSRIs and anti-psychotic agents were completed to evaluate the impact of both the copayment policy and the 30 days supply limit. The policies had a significant effect on the number of prescriptions received per 100 recipients per month but not on DDD/recipient/month for anti-manic agents. The number of prescriptions per 100 recipients/month increased after the implementation of the copayment policy and the overall increasing trend continued. This finding suggests that patients were increasing the number of prescriptions they received of this class of medications once the policies were changed. A non-significant decrease in DDD/recipient/month occurred two months post copayment policy and this trend continued. Despite this decreasing trend, the lack of significant change post-policy suggests the policies did little to alter utilization.

SSRIs were examined in a similar manner revealing that the measure, DDD/recipient/month, experienced a significant decrease two months post copayment policy and this trend continued until the end of the study. The change in utilization patterns in patients with depressive illnesses may be of particular concern to clinicians, particularly as compliance with these medications is often problematic. A decrease may indicate that patients, when faced with a copayment and days supply limits, have begun to ration their medications in an effort to save money. However, it should be noted that the mean level of utilization fluctuated at the level of 56 ddd/recipient/month pre-policy and dropped to 52 ddd/recipient/month post-policy. This indicates that though a decrease occurred, the dosing of these medications is almost double that of what would be expected. Though it is recognized that variable dosing is seen in this class of medications depending on the indication the drug is being used for, one may question whether this statistically significant decrease is actually clinically significant. The policies did not impact the number of prescriptions nor the expenditures on SSRIs.

Finally, examination of anti-psychotic class of medications revealed that the only significant change that occurred due to the policies' implementation was a decrease DDD/person two months after the copayment was implemented. However, a significant increase occurred after the days supply limits that matched the initial decrease. This fluctuation indicates that that the policies could not be attributed to this decreasing trend in utilization. The policies did not significantly impact either the number of prescriptions or expenditures on anti-psychotic medications.

These findings are different than those of other researchers evaluating the impact of cost-sharing policies in the U.S. Medicaid system (Brian & Gibbens, 1974; Chen, 1976; Hopkins et al., 1975a, 1975b; Soumerai, Avorn, Ross-Degnan, & Gortmaker, 1987; Soumerai, McLaughlin, Ross-Degnan, Casteris, & Bollini, 1994; Soumerai, Ross-Degnan, Avorn, McLaughlin, & Choodnovskiv, 1991; Soumerai, Ross-Degnan, Fortess, & Abelson, 1993; Soumerai, Ross-Degnan, Fortess, & Walser, 1997; Soumerai, Ross-Degnan, Gortmaker, & Avorn, 1990). In addition, they are different that the findings of Tamblyn et al. who studied the impact of copayments on vulnerable populations in

Quebec (Tamblyn et al., 2001). In each of these cases, copayments created a decrease in utilization that could be directly attributed to the policy. However, the process evaluation provides several rationales for why the policy may not have decreased utilization in all of the therapeutic classes that were examined. Taking a positive perspective, the policy did not impact the use of the drug categories selected in this analysis, as the policy was not intended to do so. The fact that no significant changes in utilization were found in necessary medications may substantiate that the policy had achieved what the AHRE department intended - which was the decrease in inappropriate use of medications. However, the data in this analysis cannot support such an assertion. A more likely scenario, given the triangulation of the focus groups and pharmacist survey results, is that the inability for the policy to decrease utilization in these categories may be a result of policy evasion by pharmacists and clients alike.

It is interesting to note that expenditures decreased throughout the study period in all categories except anti-psychotic agents. In general, these decreases cannot be directly attributed to the policies alone as significant decreases did not occur during the time in which the policies were implemented. The one exception is in the category of ACE inhibitors where a statistically significant decrease of approximately $620/100 recipients/month occurred two months after the copayment was implemented.

Studies on Medicaid populations in the United States have consistently shown that even minimal copayments affect the utilization of medications (Soumerai et al., 1993). One study even reported that Medicaid patients faced with cost-containment policies, chose to take non-essential medications (e.g., sedative hypnotics) instead of essential ones such as anti-hypertensives and even insulin (Soumerai et al., 1987). In the context of studies conducted on vulnerable populations, one could assert that the $2.00 copayment faced by AHRE clients would have deterred medication use.

The policy evasion evident among community pharmacists played a role in negating the impact of the policy. For example, if AHRE clients were aware of how to avoid paying the copayment and pharmacists were not complying with the policy, then it is unlikely that utilization would change appreciably. Perhaps another key issue associated with the lack of impact of the copayment and days supply policy was a function of the structure of the policy itself. Specifically, patients would only ever have to pay $6.00/month if they received three prescriptions or more in that time frame. Other copayment policies require a copayment on each prescription regardless of the number received. Furthermore, AHRE compensated each adult patient with an additional $5.00/month on their monthly support cheque. Hence, it is important to note that this feature of the policy is unique to the policy evaluation literature. The monetary compensation combined with the maximum $6.00 copayment may have assisted clients in maintaining their use of chronic medications, thereby making it impossible to see the impact of the copayment on utilization.

The use of triangulation in the policy analysis played an important role in providing insight into the process of policy implementation and the impact of the policy. Had only analysis of drug claim data been completed, one may have simply concluded that the policy was implemented correctly and access to necessary medications was not impacted. However, insight provided by the focus group and survey component of the study through triangulation provided additional information on why the policy may not have negatively impacted utilization on any of the medication classes.

Limitations

This study used three methodologies to assess the process and impact of the changes to the Alberta Human Resources and Employment drug policy. The first phase of the study involved the use of focus group methodology to reveal stakeholders' opinions about the policy. The focus groups were also used to gather information about the process of policy implementation in pharmacies, how the policy may have impacted other organizations and finally, how AHRE clients dealt with policy changes.

Some limitations exist when using focus groups to gather qualitative information. It must be recognized that the individuals who took part in this study were a volunteer sample of informants who expressed willingness to share their opinions and experiences with the researcher. Generally, all focus group participants expressed negative opinions about the policy. Individuals who believed the policy was a useful change in the administration of AHRE prescription drug coverage may not have felt compelled to participate in the focus groups and therefore did not volunteer. In this case, some positive opinions may have been excluded in the focus group discussion.

Another limitation was the method of identifying or recruiting participants for the AHRE focus group. The most efficient way to recruit individuals was to have community agencies post advertisements or have agency representatives personally recruit individuals who might be interested in participating. Obviously, this method of recruitment captured individuals who were of a specific type of AHRE client. For example, the focus group of AHRE recipients held in Edmonton was at an inner city centre so individuals participating in the group tended to be more poor or lower functioning than an individual living in the suburbs. If different methods of recruitment were used (e.g., newspaper advertisements) then clients with more varied life experiences and perspectives may have been accessed and increased the breadth of experience discussed. A final limitation was the involvement of the agency representative in one of the focus groups. Given the nature of the participants, it was felt that the agency representative's presence facilitated the interview process. In addition, given the participants apparent trust in this individual and forthright responses, it was unlikely that her presence caused them to be less truthful about their experiences.

The second phase of the study involved the survey of practicing Alberta community pharmacists. The sample was provided by the Alberta College of Pharmacists. It is unknown how many individuals completed the survey who did not actually practice community pharmacy. This may have impacted findings if non-practicing pharmacists answered the survey and they had little experience in dealing with the policy. There may also be issues with the representativeness of the survey respondents. Though the survey was administered to a random sample of pharmacists, specific types of pharmacists may have been predisposed to answering. For example, pharmacists who had more negative views of policy and/or more negative experiences with clients may have been more willing to voice their opinions compared to pharmacists who were non-committal in their opinions of the policy.

The survey was administered using a modified version of the methods outlined by Salant and Dillman (Salant & Dillman, 1994). In this study, the use of identifiers was not implemented due to concerns that identifying marks may decrease response rates because of the sensitivity surrounding the topic. This decision may have caused pharmacists to fill out more than one survey and send it in. This is unlikely due to the close proximity of mailings and the unlikelihood that the respondents would forget that they had filled out and mailed in a survey less than one month prior. Despite this assertion, the possibility remains that more than one survey from some respondents may have been received.

Limitations also emerge from the minimal use of the survey instrument. Because this instrument was developed specifically for this study, the reliability and validity of the instrument had not been evaluated prior to its use. Cronbach alpha coefficients, used to assess the internal consistency of items within each construct, ranged between 0.7 and 0.78 suggesting that the constructs did possess internal consistency.

Validity is another important factor to evaluate an instrument as it assists in determining that the instrument is measuring what the researcher intended. Three important types of validity include content validity, construct validity and criterion validity. The method used to develop the survey assured the achievement of content validity, as items were generated directly from stakeholder comments from focus groups. Criterion validity, or the measure of how well the instrument in question compares with the "gold standard measure", is not applicable in this instance as there is no reliable and valid instrument in the literature that had been utilized. However, the evaluation of construct validity may be a limitation. Construct validity is best assessed by hypothesizing how a measure should behave a priori and then analyzing the data. Several issues emerged in the evaluation of construct validity of this instrument. First, it was difficult to make a priori hypotheses in this instrument as very little research has been done evaluating the process of implementation of cost-containment policies from pharmacists' perspectives that would provide insight necessary to make a priori hypotheses. Second, it was impossible to assess whether the answers received in the survey were consistent with actual practice as there were no observational measurements completed. Future work should evaluate whether answers to the instrument may reflect what occurs in pharmacy practice. It is important to note that despite this limitation, the triangulation of qualitative and quantitative data provides some assurance of construct validity (Nolan & Behi, 1995) As was originally conceptualized by Campbell and Fiske (1959), the use of multiple methodologies may serve to provide some assurance of construct validity (Campbell & Fiske, 1959). For example, focus group data suggesting that independent pharmacies were more likely to waive the copayment was supported by survey data. Receiving similar results from different methodological approaches serves to ensure construct validity in some manner.

Time series analysis of drug claim data was used to evaluate the impact the policy may have had on utilization of medications and AHRE expenditures. The time series method also possesses limitations that are relevant to this study. Campbell and Stanley *(1963)* have outlined several factors that may jeopardize the internal and external validity of quasi-experimental design requirements. They suggest several weaknesses inherent in the use of time series experiments for the analysis of an intervention. The greatest threat to internal validity associated with this method in this study is history or the effect of events occurring during the study period besides that of the intervention. Such occurrences make it difficult to attribute changes in the series to the intervention. This time series experiment examined the impact of changes to drug policy for AHRE clients.

Though the time of the policy implementation was identified a priori, there may have been other unknown issues that affected drug utilization and expenditures. First, designating when the policy occurred and when the impact of the policy was expected is important in determining whether the policy had an impact. However, advance notice to the public via advertisements or even media coverage may have alerted clients to changes prior to the policy's implementation thereby affecting their behavior. This could result in changes in utilization not being seen when expected. Though the policy was first announced in July 1997, it does not appear that patients were given any official forewarning via communication from the AHRE ministry until just prior to the policy being implemented in November 1997. In addition focus group and pharmacist survey data would support that clients were generally unaware of the policy. Therefore, modification of client behavior prior to the policy being implemented is unlikely.

Second, changes to the formulary may have impacted net expenditures for the AHRE program. An example may be the introduction of medications into the therapeutic class such as the introduction of lowest cost alternatives or the listing of a new product within a therapeutic class. Additions to the Alberta Human Resources and Employment Drug Benefit Supplement, the formulary that guides reimbursement for medications, illustrate examples of some generic medications that may have impacted expenditures. Apo-Metformin 850mg, pms-Lithium 600mg , Gen-fluoxetine 20mg and Glyburide 2.5mg and 5mg are examples of some of the lowest cost alternatives added to the formulary during the first year of the policy. These additions may have served to decrease prices via increased competition in the marketplace. As stated earlier, the majority of therapeutic classes examined experienced a decrease in expenditures over the study period that could not be attributed directly to the policy. Further, addition of new agents within a therapeutic class (e.g., Seroquel, Wellbutrin) may also have affected utilization and expenditures, through changes in prescribing patterns. It should be noted that any changes in expenditures are likely not attributable to changes in pharmacy professional fees as these have remained constant throughout the study period.

Finally, trends in clinical use of prescription drugs may also have played a role in maintaining levels of utilization. The advent of clinical practice guidelines for diabetes have already been discussed as playing a role in maintaining or increasing utilization of select therapeutic classes. In addition, there is the possibility that prescribing patterns may be changing in a more informal manner. Though ddd/recipient/month experienced a decrease post-policy, the number of prescriptions increased overall which may be due to the preferential use of SSRIs rather than tricyclic antidepressants because of their increased availability and advantageous side effect profile. An additional example may be the use of SSRIs for other indications such as obsessive compulsive disorder or anorexia. The use of a control series may have assisted in identifying such confounders. It is doubtful, however, that a comparison series from another province's social services program would be an adequate control because of variations in the approval process of medication between provinces. For example, provincial formularies use different submission processes and different criteria for listing products. Often such changes to formularies do not coincide in each province. For this reason, fluctuations in the comparison series may be seen that would not be due to any change in policy. Nonetheless, a comparison series may have been useful to control for this limitation. Finally, changes to the clinical management of specific disease states may have played a role in the alteration of utilization patterns of medication classes. A control series would have been useful in identifying such trends as clinical practice guidelines in the management of diseases are likely not directed at only one province.

Selection is another threat to internal validity that may explain the findings. This threat occurs when the same subjects are not used for each measurement. When different subjects are involved in the measurement of each time point, it becomes more difficult to determine causality in the experiment. For example, there may be other reasons for fluctuations in utilization or expenditures that cannot be attributed directly to the policy. In this study, claims data from only those individuals who were classified as long-term recipients of AHRE were included in the analysis. Selection of recipients from long-term client categories may have assisted in assuring that clients remained on social assistance for the duration of the study making fluctuations in utilization less likely to be due to client changeover. However, it is important to note that despite this selection of AHRE categories, additional clients may have entered that category of classification and others may have left.

An additional limitation surrounding the use of administrative databases include the limited detection of outcomes (Ray, 1997). An essential component of policy analysis using administrative databases is to capture the impact of a policy on patient outcomes, such as, for example, health status, health-related quality of life and utilization of medical care. Though this study provides data on prescription drug utilization, it is not linked to patient outcomes due to the limitations associated with the database. As such, interpretations on how such a policy may have impacted the health of AHRE clients can only be hypothesized.

Recommendations to Policy makers

This study revealed shortcomings in the implementation of changes in AHRE prescription drug policy that may, in turn, have affected its intended impact. The triangulation of both data and methodological approaches assisted in providing a comprehensive policy evaluation of both the process of policy implementation and the impact of the policy from a variety of stakeholder viewpoints and via the analysis of drug claim data. This policy evaluation has generated four key recommendations for the implementation of future polices in the Alberta Human Resources and Employment prescription drug program.

First, AHRE should ensure that there is an adequate method of disseminating policy changes to stakeholders. The lack of awareness of the policy was highlighted by focus group data from AHRE clients, pharmacists and health care and community agency representatives. In addition, frustration with the administration and implementation of the policy was evident in the survey of community pharmacists as well as the focus groups with other stakeholders (i.e., AHRE clients, pharmacists and community and health care agency representatives). Ensuring that AHRE clients are advised of future policy changes is imperative to alleviate the additional stress that pharmacists or other providers impacted by policy changes may face by having to explain the policy to clients on a regular basis. As well, ensuring clients were made aware of the policy prior to implementation may have encouraged clients to budget for expenditures on prescription medications each month.

The focus group discussions revealed modifications to advertising that may have increased client awareness and understanding of the policy. For example, clients received written notification of the policy changes prior to their implementation. Such an advertising mechanism may have excluded clients who were illiterate or not fluent in English from understanding the policy changes. A final point about the advertising of the policy would be to suggest that the implementation of such policy be introduced in isolation of other policy changes affecting AHRE clients. In fact, one representative of an inner city agency suggested that the requirement for bank accounts was of such concern that her clientele were unaware of any drug policy changes. Though this concern likely affected only a small number of AHRE clients, it illustrates that particularly vulnerable populations may find it difficult to keep track of or apply a variety of changes to AHRE policy occurring within a short time frame.

The second policy recommendation is for AHRE to introduce some mechanism that will ensure pharmacists or other providers are complying with the policy. Both focus groups findings and the pharmacist survey suggest that there is variability in administering the copayment portion of the policy. For example, some pharmacists waive the fee for emotional reasons, while others do so to generate additional AHRE prescription revenue. Violations of copayment policies in this manner create several problems. First, pharmacies may begin to compete for AHRE clientele by violating the policy. Focus group data supports this assertion, as it was evident that AHRE clients were aware of pharmacies that violated the policy and often made it a point to frequent them. In addition, clients believed that small, independent stores were more likely to waive the fee than large retail, chain or grocery store pharmacies - a finding that is supported by the survey results. Such violations create an atmosphere of unfair competition between pharmacies and create rifts between practitioners. Second, and perhaps more importantly, waiving the copayment is likely to negate the intended impact of the policy. For example, if AHRE clients can find pharmacies that will waive the fee for them, they may continue to use prescription medications in the same manner prior to the policy being implemented. This will create a situation where the policy has little to no impact on drug utilization.

The third recommendation is that future drug policy changes should be framed more clearly to achieve the goal of the policy initiative. Research on drug policy changes (Soumerai et al., 1993) in the U.S. Medicaid system suggested that copayments for prescription drugs are an effective means of decreasing utilization. Though one study has indicated that copayments have a negative effect of the use of essential medications, there is little evidence in the North American peer–reviewed literature to support that such policies negatively impact the health of patients. Shortcomings in the process of policy implementation by the AHRE department and application of policy within pharmacies may have some bearing on the lack of impact seen in utilization.

It is worthwhile to note that patients received an additional $5.00 on their monthly allowance cheques to compensate for their prescription medication copayments. This additional funding may have been enough to cause patients to be unconcerned with the copayment and therefore not effect utilization. If control of utilization was the primary goal of this policy, then simply implementing the copayment and not adding the additional $5.00 may have better served AHRE.

Related to the third recommendation is the concern that the $5.00 allowance given to clients in this manner made the policy seem nonsensical to the stakeholders. One may argue that if stakeholders, such as pharmacists, believed the policy to be ineffective on its face, then they would be less likely to comply with it. Focus group and survey data reflect that stakeholders did not understand the rationale behind the addition of $5.00 to clients' cheques. Clients themselves found it confusing and some even asserted that it seemed patronizing. For example, one client suggested that implementing the policy in that manner made it appear that AHRE was trying to "teach" them something. If the goal is to control drug utilization, a straightforward copayment policy without compensation directed to the client should be used.

Finally, an alternative cost containment mechanism should be implemented that avoids unfairly penalizing individuals who are responsibly using their prescription medications. Focus group data provided information about how the copayment could be evaded. Both AHRE clients and pharmacists believed that individuals prone to abusing medications were able to avoid the copayment and still receive the additional $5.00. For example, pharmacists had specific examples of instances where they believed patients did not fill prescriptions in order to spend $5.00 for other things that the family needed. Suggestions for other means of controlling drug utilization and expenditures included, for example, restricting patients to one pharmacy or using a mechanism similar to We//net that would allow health care practitioners to monitor and encourage appropriate drug utilization. If ensuring appropriate utilization of medication for AHRE clients is the goal of future policy, perhaps such initiatives could be used. In that manner, stakeholders will perceive that clients are being treated equitably and that the goal of ensuring appropriate drug therapy is met.

Future Research

There are several directions for future policy research that may build on the strengths of this particular study and avoid its weaknesses. Little policy analysis has been completed that evaluates the impact of drug plan changes on vulnerable populations in Canada. In addition, there is little process evaluation of similar policies in this country. This study has added to the literature as it provides insight about policy implementation in the Canadian setting and allows policy makers to have a better understanding of implementing a similar policy in the future. An additional strength is that the study used time series analysis to evaluate the impact the policy on drug utilization and examined how the policy may have impacted utilization.

It may be difficult to generalize the findings of this study beyond the Alberta experience. The policy implemented in Alberta is unique as it required a copayment from social services clients but provided them with an additional five dollars to compensate for the copayment. Though aspects of the findings may be applied in some instances, (e.g., improved policy dissemination) the impact of this policy may not be applied directly to other cost-containment policies, particularly those that do not provide monetary compensation for copayments. Generalizability of findings to other populations and health care systems may also be problematic due to differences in the administration of health care services and medication distribution. However, findings of the process evaluation may provide some insight for policy makers regarding behavior of health care professionals faced with copayments or policy dissemination.

An additional consideration for future research is the inclusion of other therapeutic categories that may be considered non-essential. Such an evaluation was completed by Soumerai and colleagues in (1987) and evidence was found that clients used non-essential medications preferentially over those that were termed as essential. It would have been useful to have such information available in the time series analysis component of this study (Soumerai et al., 1987). These product categories were not selected for evaluation because initial meetings between the researcher and stakeholders (e.g., The Alberta Pharmaceutical Association, George Spady Centre) voiced specific concerns about the impact of the policy on the use of essential or chronic medications. In addition, medications with the potential for inappropriate use such as sedatives or analgesics still may be used by patients appropriately. It was felt that without individual patient identifiers and related diagnostic codes from Alberta Health and Wellness, it would be difficult to differentiate those medications used appropriately and inappropriately. The lack of impact on the policy in the chosen therapeutic categories may have been due to the fact that clients were using non-essential medications more sparingly to ensure that they had enough money to afford their essential medications. Future research should ensure that a broad variety of therapeutic categories are examined.

Finally, a view to incorporate prospective policy research initiatives into the policy conception of policies and the policy implementation process would be an asset in ensuring that policy initiatives are adequately evaluated and evidence-based. Researchers and policy makers working in concert would possess the capability of ensuring that policy analyses were relevant to the stakeholders as well as timely.

This study examined the process of policy implementation and evaluated the impact the policy had on drug utilization and expenditures. This study did not look beyond the impact on drug utilization to the possible effects on utilization of health care services or services of other organizations such as nursing homes. Thus, this study did not complete an efficiency evaluation. Future research should strive to provide a comprehensive view of the policy to ensure that each of process, impact and efficiency are addressed in any research initiative. In this manner, a more exact picture of the policy and its repercussions may have been derived. Had data been available about physician visits, hospital admissions and other health care expenditures, one could evaluate whether restrictions in the prescription drug program caused an increase in use of other health care sectors, as has been shown in U.S. Medicaid studies (Soumerai et al., 1993).

Conclusion

A policy analysis of changes to the Alberta Human Resources and Employment drug policy program was conducted that revealed several key findings. Process evaluation suggested that though only 3.1% of pharmacies had a store policy to waive the fee some pharmacists did evade the policy. Evidence gathered from focus group interviews indicated that reasons for policy evasion ranged from concern regarding patients' well-being if they were unable to afford medications to the retention of AHRE clientele for business purposes. Specific pharmacy and pharmacist characteristics were identified in both the survey and focus group components of the study that described pharmacists as more likely to waive the fee. It appeared that pharmacists working in small, independent pharmacies may be more pre-disposed to policy evasion than those working in large retail, grocery or chain stores. In the future, mechanisms to enforce pharmacist compliance with the copayment policies may be advisable if a cost-sharing policy is to have the desired effect.

AHRE beneficiaries were also identified as participating in policy evasion. Focus group data indicated that clients felt the policy was unfair, particularly given their limited incomes. Clients seem to be using the extra funds provided by the AHRE program for prescription medications for other necessities, rather than saving the money for prescriptions. In such circumstances it may be understandable why some clients feel compelled to try to avoid the copayment. Interestingly all stakeholders interviewed felt that this particular AHRE policy likely had little impact on those clients who abused medications or used them inappropriately. Finally, ineffective dissemination of the policy may have also impacted its implementation. Data from focus group interviews indicated that the policy was not understood by many of the clients and that clients were generally unaware of the policy. This, in turn, caused frustration in the pharmacy as pharmacists where forced to explain the policy repeatedly.

An impact evaluation found that the $2.00 copayment did not have a negative impact on the use of anti-diabetics and ACE inhibitors. In fact, measures of utilization including the number of prescriptions/100 recipients/month and ddd/recipient/month showed increasing trends despite the policy implementation. An evaluation of the impact of the copayment and days supply limits suggested a potentially negative impact on the utilization of SSRIs in the measure of ddd/recipient/month. Such a change in utilization patterns may be a concern, particularly in the case of a class of medications used for depressive illness and other psychological disorders where close monitoring and compliance is key in its management. However, one may question whether this finding is clinically significant given the relatively high doses evident in this population.

The analysis of the AHRE policy provides valuable information in the process of policy implementation and the impact of cost-sharing policies on essential medications. This cost-containment policy was unique in that it limited days supply and required a copayment but provided partial financial compensation for prescription medications. Data and methodological triangulation played an integral part in providing insight into the entire process of policy implementation and, in turn, its impact on drug utilization. Triangulation ensured that the information on the process of policy implementation was complete and includes a variety of stakeholders' perspectives. In addition, confirmation of findings was achieved by the triangulation of different methodologies in the process and impact evaluations.

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Appendix A

Question Guide for AHRE clients

Social Services Clients Focus Group questions

Introduction:

My name is Carlyn and I will be leading the discussion today. This is my assistant,________, who will be helping me and taking some notes while we talk. We will be taping the discussion today so that we don't forget what you have said. The tapes will be typed out after and all your names and other things that you said that might identify you will be removed.

Confidentiality is very important in this study. My assistant and I will keep all the information mentioned in this discussion confidential and we expect that you will not discuss what was said here outside of the groups either.

You have been invited to take part in this discussion group because you have had experience in dealing with Alberta Social Services drug policy. This discussion will probably take about one and a half to two hours and will ask you about what you think of the drug policy, what your experiences are with the policy and pharmacists. Finally, we'll ask you to come up with some ideas about how we could control the province's drug costs.

If you don't feel comfortable answering some of the questions, then please feel free not to. Also, if you don't want to be in the focus group anymore, then you are free to leave.

1) In order to get to know each other I thought it would be a good idea to go around the table/room and tell each other our names.
2) Does anyone want to volunteer to tell me what you know about the drug plan that Alberta Family and Social Services offers you?
3) About how many prescriptions do you and your family (if applicable) get filled in a month?
   Probe: Do you visit one pharmacy or do you go to different pharmacies?
4) Do you remember the first time you were asked to pay the co-payment by the pharmacist? What was that like?
5) Does the pharmacist ask you to pay the $2.00 co-payment when you get your prescriptions filled?
   Probe: If not, why not?
6) Have you ever had experiences getting medications where the AFSS policy made it difficult to do so? (i.e., lack of money, hard to get to pharmacy to refill often)
   Probe: Why was it difficult?
   What did you do?
7) In general, what do you think of the pharmacist(s) you deal with? (i.e., how they treat you? how they ask for the co-payment?)
8) On the paper in front of you write down three positive things about the AFSS drug policy. What are they?
9) On the paper in front of you write down three negative things about the AFSS drug policy. What are they?
10) Do you think that AFSS drug policy has negatively or positively affected your access to prescription drugs? Medical care? Has it affected it at all?
11) Are there any suggestions that you could make to the Alberta government about a better way to control drug costs? What are they?
12) Is there anything that you would like to add or anything that you think we may have missed?

Appendix B

Health Care and Community Agency Representative Focus Group – Question Guide

Focus group questions for health care agency and community agency representatives

Introduction:

My name is Carlyn and I will be leading the discussion today. This is my assistant,________, who will be helping me and taking some note while we discuss. We will be taping the discussion today so that we don't forget what you have said. The tapes will be typed out after and all your names and other things that you said that might identify you will be removed.

Confidentiality is very important in this study. My assistant and I will keep all the information mentioned in this discussion confidential and we expect that you will not discuss what was said here outside of the groups either.

You have been asked to be a part of this discussion group because you have had experience in your workplace/agency dealing with individuals who are affected by the AFSS drug policy. The discussion will probably take about one and a half to two hours and will touch issues like how you perceive the policy affected your clients and agency.

If you feel that you don't want to answer a question, you do not have to. Also, if you feel that you do not want to take part in the discussion you are free to leave at any time.

1) In order to get to know each other a little bit better, could we go around the table, say our names tell what agency we are from?
2) Can you tell me what you know about the AFSS drug policy?
3) Can you relate any "stories" about the drug policy and/or its administration that have been conveyed to you by clients?
4) How do you believe the policy has impacted your agency's clients? Positive? Negative?
5) Has the policy impacted your practice in your agency? How?
   Probes: increased use of your agencies?
6) How do you feel the policy has impacted the services your agency provides?

Pharmacists are the professionals who are required to ask for reimbursement for the prescription drugs in the AFSS drug policy.

7) What are some possible benefits of having pharmacists perform this role?
8) What are some possible negative aspects of having pharmacists perform this role?
9) Name three positive things about the AFSS drug policy.
10) Name three negative things about AFSS drug policy.
11) Do you think that the drug policy has affected AFSS clients access to prescription drugs? Medical services?
12) Are there any drug use or pharmacy issues among your clients (perhaps even unrelated to drug policy) that you think need to be addressed? What are they?
13) Is there anything that you want to add to the discussion or anything that you feel we may have missed?

Appendix C

Pharmacist Focus Group Question Guide

Pharmacist focus group questions

My name is Carlyn and I will be leading the discussion today. This is my assistant,________, who will be helping me and taking some note while we discuss. We will be taping the discussion today so that we don't forget what you have said. The tapes will be typed out after and all your names and other things that you said that might identify you will be removed.

Confidentiality is very important in this study. My assistant and I will keep all the information mentioned in this discussion confidential and we expect that you will not discuss what was said outside of the groups either.

You have been chosen to take part in this focus group discussion because of your insight into AFSS drug policy and AFSS clients. Your opinions are particularly important in understanding how the policy is implemented as pharmacists are charged with the responsibility of administering the policy on a daily basis. The answers to your questions will be used in creating a province wide survey of pharmacists' attitudes toward the policy, AFSS clients and AFSS policy administration.

1) In order to get to know each other a little better, perhaps we could go around the group and say our names and how long we have practised community pharmacy.
2) What are the positive aspects of the implementation of the AFSS drug policy?
3) Write down three main problems that spring to mind in the policy's *implementation*. What were they? (for example, clients didn't know about the policy)
4) Do you think there are any negative aspects of the policy itself?
5) Tell me about some of the AFSS clients that come into your store. What are they like?
6) How have the AFSS clients that come to your pharmacy deal with the policy change?
   Probe: Do they selectively fill prescriptions?
   Do they ask to have fee waived?
7) Do you believe that all pharmacies are implementing the policy in the same manner? (i.e., are some pharmacies waiving the fee?, letting people run tabs?)
8) What do you think of pharmacies/pharmacists who waive the fee?
9) Do you think that AFSS policy has affected clients' access to prescription drugs? Medical services? How so?
10) Do you have any suggestions for different ways of controlling drug costs?
11) Is there anything that we have missed that you would like to add?

Appendix D

Study Information Sheet and Informed Consent – AHRE clients

Study Information Sheet

Principal Investigator:
Carlyn I. Volume, B.Sc. Pharm., M.Sc.
Ph.D. Candidate, Faculty of Pharmacy and Pharmaceutical Sciences,
University of Alberta
Co-investigator:
Karen B. Farris, B.S. Pharm., Ph.D.
Associate Professor, Faculty of Pharmacy and Pharmaceutical Sciences,
University of Alberta

Purpose:
You are being asked to take part in a group discussion to learn about what you think about Alberta Human Resources and Employment prescription drug plan. We are doing this study because we want to know what you think about the plans and how they may have affected your life. We also want to know what ideas you might have about how the Alberta government could control drug costs.

Procedures:
To be a part of the study you need to:

1) complete a survey that asks you things like your age, sex and the number of medications you are on.
2) take part in a group discussion that will take one or two hours where we will ask your opinions about the Social Services drug plan. We will also ask you about what kind of things the Alberta government might do to decrease drug costs.

Possible benefits
The possible benefit to you will be that the information you give will be reported to Alberta Human Resources and Employment and what you say might be taken into consideration by them. Your experiences with pharmacists may also be included in a survey that we are doing with Alberta pharmacists. The information that you give us may help teach Alberta pharmacists how to deal with Social Services clients better.

Possible risks
The rest of the discussion group will know what your opinions are about AFSS drug policy.

Confidentiality
The survey that you fill out will be kept confidential and you should not put your name on it. The audiotapes of the discussion will be kept in a locked cabinet that only the principal investigator has access to. Any report that is published about this study will not have any names on it.

We would be grateful if you would take part in the study. If, for whatever reason, you want to stop being in the study, you can leave at any time.

If you have any concerns about anything in this study, you can contact The Patient Concerns Office of the Capital Health Authority at 474-8892. This office is not related to any of the researchers in this project.

Please contact the researchers below if you have any questions about the study.

Carlyn I. Volume, B.Sc. Pharm., M.Sc.
Ph.D. Candidate
Faculty of Pharmacy and Pharmaceutical Sciences
University of Alberta

Phone: (780) 492-0092
Fax: (780) 492-3007

Consent Form

Title of the Project: Evaluating AHRE drug policy changes and their implementation: perceptions of stakeholders and drug use trends

Principal Investigator:
Carlyn I. Volume, B.Sc. Pharm., M.Sc.
Ph.D. Candidate, Faculty of Pharmacy & Pharmaceutical Sciences, University of Alberta
(780) 492-0092

Co-investigator: (supervisor)
Karen B. Farris, B.S. Pharm., Ph.D.
Associate Professor, Faculty of Pharmacy & Pharmaceutical Sciences, University of Alberta
(780) 492-2020

Supervisory committee:
K.C. Carriere, Ph.D
  Associate Professor, Dept. of Mathematical Sciences, University of Alberta
J. Church, Ph.D.
  Director of Graduate Training, Assistant Professor
  Department of Public Health Sciences, University of Alberta
J.A. Johnson, Ph.D.
  Assistant Professor, Faculty of Pharmacy and Pharmaceutical Sciences

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Do you understand that you have been asked to be in a research study?	Yes	No
Have you read and received a copy of the attached Information Sheet?	Yes	No
Do you understand the benefits and risks involved in taking part in this research study?	Yes	No
Have you had the opportunity to ask questions and discuss this study?	Yes	No
Do you understand that you can withdraw from the study at any time?	Yes	No
Has the issue of confidentiality been explained to you? Do you understand who will have access to the surveys and audio-tapes?	Yes	No

This study was explained to me by:_______________________

I agree to take part in this study.

______________________________ ____________ ______________________________
signature of research participant date witness

______________________________ ______________________________
printed name of research participant signature of witness

I believe that the person signing this form understands what is involved in this study and voluntarily agrees to participate.

______________________________ ____________
signature of investigator or designee date

Appendix E

Study Information Sheet and Informed Consent Form – Health Care and Community Agency Representatives

Evaluating AFSS drug policy changes: perceptions of stakeholders and drug use trends

Principal Investigator:
Carlyn I. Volume, B.Sc. Pharm., M.Sc.
Provisional Ph.D. Candidate, Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta
Co-investigator:
Karen B. Farris, B.S. Pharm., Ph.D.
Associate Professor, Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta

Purpose

You are being asked to take part in a discussion to gather information about how you believe Alberta Family and Social Services drug policy has affected your clients and the agency you work for. We are doing this study to examine the effect of AFSS drug policy on clients and drug use trends. We are also surveying pharmacists to understand how they implemented the drug plans. Some of your comments may also be included in the pharmacy survey.

Procedures

Your participation in this study will involve:

1) completing a demographic questionnaire. The questionnaire asks information like your age, sex and role in the agency.

2) taking part in a group discussion about how you believe the AFSS drug policy may or may not have affected your AFSS clients and/or the agency you work for. The discussion will last one to two hours. You have the right to refuse to answer any question.

Possible benefits

Information gained in the discussion group will be used to learn more about the impact of drug co-payment policies on AFSS clients and the agencies that serve them. In addition, some of the information you give us may be included in a pharmacy survey that looks at how Alberta pharmacists deal with AFSS clients and the drug policy. Alberta Family and Social Services will receive a final report of the project.

Possible risks

Your beliefs about the Alberta Family and Social Services drug policy and how it affected your agency and clients will be known to the rest of the discussion group.

Confidentiality
The survey that you fill out will be kept confidential and will simply be used to describe the group. Please do not put your name on it. The audiotapes and transcripts of the discussion will be kept in a locked cabinet for seven years after the completion of the study. Only the principal investigator will have access to the audiotapes. Any report published about the study will not have any names on it. All information will be held confidential except when professional codes of ethics and/or legislation requires reporting.

We would be grateful if you would take part in the study. If, for whatever reason, you want to stop being in the study, you can leave at any time.

If you have any concerns about anything in this study, you can contact The Patient Concerns Office of the Capital Health Authority at (780) 407-1040. This office is not affiliated with any member of the research team.

Please contact the researcher below if you have any questions about the study.

Carlyn I. Volume, B.Sc.Pharm., Ph.D.
Provisional Ph.D. Candidate
Faculty of Pharmacy and Pharmaceutical Sciences
University of Alberta

Phone: (780) 492-0092
Fax: (780) 492-3007

Consent Form

Title of the Project: Evaluating AFSS drug policy changes and their implementation: perceptions of stakeholders and drug use trends

Principal Investigator:	Carlyn I. Volume, B.Sc. Pharm., M.Sc. Provisional Ph.D. Candidate, Faculty of Pharmacy & Pharmaceutical Sciences, University of Alberta (780) 492-0092
Co-investigator: (supervisor)	Karen B. Farris, B.S. Pharm., Ph.D. Associate Professor, Faculty of Pharmacy & Pharmaceutical Sciences, University of Alberta (780) 492-2020

Supervisory committee:
K.C. Carriere, Ph.D
  Associate Professor, Dept. of Mathematical Sciences, University of Alberta
J. Church, Ph.D.
  Director of Graduate Training, Assistant Professor
  Department of Public Health Sciences, University of Alberta
J.A. Johnson, Ph.D.
  Assistant Professor, Faculty of Pharmacy and Pharmaceutical Sciences

---

Do you understand that you have been asked to be in a research study?	Yes	No
Have you read and received a copy of the attached Information Sheet?	Yes	No
Do you understand the benefits and risks involved in taking part in this research study?	Yes	No
Have you had the opportunity to ask questions and discuss this study?	Yes	No
Do you understand that you can withdraw from the study at any time?	Yes	No
Has the issue of confidentiality been explained to you? Do you understand who will have access to the surveys and audio-tapes?	Yes	No

This study was explained to me by:________________________

I agree to take part in this study.

signature of research participant   date   witness

printed name of research participant   signature of witness

I believe that the person signing this form understands what is involved in this study and voluntarily agrees to participate.

signature of investigator or designee   date

Appendix F

Study Information Sheet and Informed Consent Form – Pharmacists

Evaluating AFSS drug policy changes: perceptions of stakeholders and drug use trends

Principal Investigator:
Carlyn I. Volume, B.Sc. Pharm., M.Sc.
Provisional Ph.D. Candidate, Faculty of Pharmacy and Pharmaceutical Sciences,
University of Alberta
Co-investigator:
Karen B. Farris, B.S. Pharm., Ph.D.
Assistant Professor, Faculty of Pharmacy and Pharmaceutical Sciences,
University of Alberta

Purpose:

You are being asked to take part in a group discussion to help us develop a survey that we will give to Alberta pharmacists. The discussion will focus on what you think about Alberta Family and Social Services (AFSS) drug policy and AFSS clients. We will also discuss how you administered the policy in your pharmacy.

Procedures:

To be participate in the study you need to:

1) complete a survey that asks you things like you age, sex and years of pharmacy practice.
2) take part in a group discussion that will take one to two hours where we will ask you your opinions about the Alberta Family and Social Services drug plan and AFSS clients in general. We will also ask you about any good or bad experiences you may have had with this policy and how you administer this policy in your store.

Possible benefits

The possible benefit to you will be that the information you give will be made into a survey that will ask Alberta pharmacists their opinions about the AFSS drug policy and how they implement it in their pharmacy. The discussion you are participating in will help us know what questions to ask them. A final report of the project will be provided to Alberta Family and Social Services.

Possible risks

The rest of the discussion group will know your beliefs about AFSS policy and AFSS, as well as how you administer the policy in the pharmacy.

Confidentiality

The questionnaire that you fill out will be kept confidential and will be used simply to describe the group. Do not put your name or the name of the pharmacy you work for on the questionnaire. The audiotapes and transcripts of the discussion will be kept in a locked cabinet that only the principal researcher has access to. Any report published about this study will not have any names on it. All information will be held confidential except when professional codes of ethics and/or legislation require reporting.

We would be grateful if you would take part in the study. If, for whatever reason, you want to stop being in the study, you can leave at any time.

If you have any concerns about anything in the study, you can contact The Patient Concerns Office of the Capital Health Authority at (780) 407-1040. This office is not affiliated with any of the researchers in this project.

Please contact the researcher below if you have any questions about the study.

Carlyn I. Volume, B.Sc.Pharm., M.Sc.
Provisional Ph.D. Candidate
Faculty of Pharmacy & Pharmaceutical Sciences
University of Alberta

Phone: (780) 492-0092
Fax: (780) 492-3007

Consent Form

Title of the Project: Evaluating AFSS drug policy changes and their implementation: perceptions of stakeholders and drug use trends

Principal Investigator:	Carlyn I. Volume, B.Sc. Pharm., M.Sc. Provisional Ph.D. Candidate, Faculty of Pharmacy & Pharmaceutical Sciences, University of Alberta (780) 492-0092
Co-investigator: (supervisor)	Karen B. Farris, B.S. Pharm., Ph.D. Associate Professor, Faculty of Pharmacy & Pharmaceutical Sciences, University of Alberta (780) 492-2020

Supervisory committee:
K.C. Carriere, Ph.D
  Associate Professor, Dept. of Mathematical Sciences, University of Alberta
J. Church, Ph.D.
  Director of Graduate Training, Assistant Professor
  Department of Public Health Sciences, University of Alberta
J.A. Johnson, Ph.D.
  Assistant Professor, Faculty of Pharmacy and Pharmaceutical Sciences

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Do you understand that you have been asked to be in a research study?	Yes	No
Have you read and received a copy of the attached Information Sheet?	Yes	No
Do you understand the benefits and risks involved in taking part in this research study?	Yes	No
Have you had the opportunity to ask questions and discuss this study?	Yes	No
Do you understand that you can withdraw from the study at any time?	Yes	No
Has the issue of confidentiality been explained to you? Do you understand who will have access to the surveys and audio-tapes?	Yes	No

This study was explained to me by:______________________

I agree to take part in this study.

signature of research participant	date	witness
printed name of research participant		signature of witness

I believe that the person signing this form understands what is involved in this study and voluntarily agrees to participate.

signature of investigator or designee	date

Appendix G

Demographic Questionnaire – AHRE Clients

AHRE client demographic questionnaire

1) What is your age? ___________ years

2) Sex ☐ Male
☐ Female

3) Are you? ☐ married
☐ single
☐ widowed
☐ divorced

4) Do you have children or other dependents? ☐ Yes ☐ No

If so, how many of them live with you? ___________

5) How long have you been on Social Services (Alberta Human Resources and Employment)? ______________________

6) How many prescriptions do you **usually** get filled every month? ______

Appendix H

Demographic Questionnaire – Health Care and Community Agency Representatives

Agency demographic questionnaire

1) Sex: ☐ Male

   ☐ Female

2) What is your educational training? (i.e., nurse, social worker, physician) ________

3) Which agency do you work for? ________________________

4) How long have you worked for this agency? ___________years

5) Approximately what percentage of the time do you deal with AFSS clients?

   ________________%

6) Do you have any other comments about the AFSS policy or another related issue that you did not feel comfortable sharing with the group? If you would like, please feel free to comment below.

Appendix I

Demographic Questionnaire – Pharmacists

Pharmacist demographic questionnaire

1) How long have you practiced pharmacy?_________ years

2) Sex: ☐ Male

☐ Female

3) Do you work in: ☐ Chain (i.e., London Drugs, Shopper's)

☐ Grocery/Retail (i.e., Safeway, Walmart)

☐ Independent (i.e. Bob's Pharmacy)

☐ Other _____________

4) What percentage of your prescriptions belong to Social Services clients? _______%

5) Is there anything else about this discussion that you didn't feel comfortable discussing in the group? If so, please feel free to comment below.

Appendix J

Survey Instrument

The purpose of this survey is to describe pharmacists' opinions of the changes made to the Social Services drug plan and to describe how the plan has been implemented in pharmacies across Alberta. If you work at more than one community pharmacy, please reflect on your experiences in the pharmacy where you spend the **majority of your time working** when you answer this survey. Some statements may sound the same. Your responses will be completely anonymous. Do not write your name on the survey.

These questions are to help us describe the type of pharmacists who participated in this survey.

1) What is your age?_____ years

2) Are you? male female

3) In what type of pharmacy do you practice?

chain (e.g., Shopper's Drug Mart, London Drugs)
grocery/retail (e.g., Safeway, Walmart, Superstore)
independent (e.g., Bob's pharmacy)
other _______________

4) How many hours a week do you work in a community pharmacy?

10 hours or less per week

11 to 20 hours per week

21 to 30 hours per week

31 to 40 hours per week

greater than 40 hours per week

5) Are you?

Store owner

Manager

Staff pharmacist

6) How long have you practiced pharmacy? _______ years

7) What percentage of the patients that you provide prescriptions to receive assistance from Alberta Human Resources and Employment patients (formerly Alberta Family and Social Services patients) ________%

Social Services patients receive drug benefits from Alberta Human Resources and Employment (formerly Alberta Family and Social Services) for their prescription medications. Prior to November 1997, Social Services patients received prescription medications free of charge. In 1997 and 1998 their drug plan was changed, and adult patients are now required to pay $2.00 for the first three prescriptions each month. In addition, there are days supply limits that vary for certain medications (i.e, 30 days supply for antidepressants, 100 days supply limits for ACE inhibitors).

The following statements are about the Social Services drug plan, why it was put in place and how it is functioning. Please indicate the extent to which you AGREE or DISAGREE with each statement in the survey by circling the appropriate number.

	strongly disagree	disagree	neutral	agree	strongly agree
Most Social Services patients have not been well informed about the drug plan changes.	1	2	3	4	5
In general, most doctors are aware of the Social Services drug plan changes.	1	2	3	4	5
Pharmacists should be provided with written material to assist them in explaining the drug plan changes to Social Services patients.	1	2	3	4	5
Social Services drug plan changes were put in place to prevent medication wastage.	1	2	3	4	5
Instead of drug plan changes to control costs for Social Services patients, pharmacists should be paid to provide pharmaceutical care for them.	1	2	3	4	5
Adult Social Services patients should not receive the extra $5.00 per month to partially cover their medication expenses.	1	2	3	4	5
The days supply limits are reasonable.	1	2	3	4	5
The $2.00 co-pay per prescription is too much for Social Services patients to pay for medications.	1	2	3	4	5
A percentage co-pay would be better than the $2.00 co-payment.	1	2	3	4	5

	strongly disagree	disagree	neutral	agree	strongly agree
I think that the $2.00 co-payment is reasonable.	1	2	3	4	5

The following statements are about the effect of the drug plan changes on Social Services clients. Please indicate the extent to which you agree or disagree with the following statements by circling the appropriate number.

	strongly disagree	disagree	neutral	agree	strongly agree
The drug plan changes have been successful in helping Social Services patients to be responsible with their money.	1	2	3	4	5
The drug plan changes have been successful in preventing individuals who abuse medications from accessing as many prescription drugs.	1	2	3	4	5
The majority of Social Services patients find ways of avoiding payment of the $2.00 co-pay.	1	2	3	4	5
The drug plan changes prevent Social Services patients from getting essential medications (e.g. antihypertensives) that they need.	1	2	3	4	5
The drug plan changes have caused a real financial hardship for some of my patients.	1	2	3	4	5
Drug abusers on Social Services are still abusing the system, while honest Social Services patients are being punished for needing prescriptions.	1	2	3	4	5
The drug plan changes encourage individuals to be more responsible with their health expenses.	1	2	3	4	5
The drug plan changes act as an incentive for Social Services patients to avoid getting prescriptions.	1	2	3	4	5
The drug plan changes have been successful in helping Social Services patients become aware of costs of medications.	1	2	3	4	5

The following statements are about the administration of the Social Services drug plan in pharmacies. Please indicate the extent to which you agree or disagree with each statement by circling the appropriate number.

	strongly disagree	disagree	neutral	agree	strongly agree
Pharmacies should have the right to waive the $2.00 fee if they want.	1	2	3	4	5
The work required to administer this plan in my pharmacy is no different than the work required to administer any other plan (e.g., ASSURE, Alberta seniors drug plan)	1	2	3	4	5
Pharmacies should be policed in some way to ensure that they are following the drug plan.	1	2	3	4	5
There should be penalties for pharmacies that violate the drug plan that requires Social Services patients to pay $2.00.	1	2	3	4	5
The variability with some pharmacies charging the fee and others not charging it is good to promote competition between pharmacies.	1	2	3	4	5
Pharmacists should work together to have the $2.00 co-pay removed because it is unfair to Social Services patients.	1	2	3	4	5
Pharmacists should work together to have the $2.00 co-pay removed because it is too much of a burden for pharmacists to administer.	1	2	3	4	5

The following questions ask you about your perceptions of Social Services patients. Please circle the appropriate answer that describes the extent to which you agree or disagree with the following statements.

	strongly disagree	disagree	neutral	agree	strongly agree
In general, I understand what Social Services patients are going through.	1	2	3	4	5

	strongly disagree	disagree	neutral	agree	strongly agree
Most Social Services patients are just trying to use the Social Services system.	1	2	3	4	5
The majority of Social Services patients are trying to "get back on their feet" to get off Social Services.	1	2	3	4	5
In general, I believe that Social Services patients are irresponsible with their money.	1	2	3	4	5
There are only a small percentage of Social Services patients that are abusing the Social Services system.	1	2	3	4	5
Social Services patients need to learn to be responsible for their money.	1	2	3	4	5

The following are statements about the administration of the Social Services drug plan. Please indicate the frequency that you carry out these activities.

	never	some of the time	a good bit of the time	most of the time	all the time
I have to explain the drug plan to the majority of Social Services patients.	1	2	3	4	5
I charge the $2.00 co-payment to my Social Services patients.	1	2	3	4	5
I am afraid to enforce the policy because I fear physical harm might come to me.	1	2	3	4	5
It is hard to collect the required co-payment from my Social Services patients because I feel sorry for them.	1	2	3	4	5
It is hard to collect the required co-payment from my Social Services patients because they always argue with me about it.	1	2	3	4	5

	never	some of the time	a good bit of the time	most of the time	all the time
We allow Social Services patients to "run a tab" for their medication co-payments.	1	2	3	4	5
I work with my Social Services patients to create a payment plan for unpaid co-payments that is amenable to both of us.	1	2	3	4	[✓ 5]
I find ways of giving more than the days supply limit to my Social Services patients.	1	2	3	4	5

The following question is about your pharmacy's policy of charging the co-payment for Social Services patients. Please answer yes or no to the best of your knowledge remembering that your response will be kept anonymous.

	yes	no	don't know
It is a store policy to **WAIVE** the $2.00 co-pay for the adult Social Services patients.	1	2	3

Thank you for your participation in this study. This information will form part of a comprehensive analysis of the effects of Social Services drug policy changes. Please feel free to make any additional comments that you may have about Social Services drug policy or the survey itself in the space provided below and on the final page of the survey.

Appendix K

Survey Cover Letter

March 30, 2000

Dear «first_name»,

As a practicing community pharmacist you are probably aware of the Alberta Human Resources and Employment (formerly Alberta Family and Social Services) drug plan. This plan requires adult patients to pay $2.00 for the first three prescriptions each month. In addition, this plan has different days supply limits for specific medications. For example, some antibiotics have a 14-day supply limit while an ACE inhibitor has a 100-day supply limit. Adult clients enrolled in this program receive an additional $5.00 on their monthly assistance cheques to partially compensate for the cost of prescriptions.

I am conducting a study entitled, *Evaluating AHRE drug policy changes and their implementation: perceptions of stakeholders and drug use trends*, that is evaluating the impact of the changes outlined above on drug utilization. Knowing what pharmacists think of this drug plan and how they administer it in their pharmacies is vital to assessing the success of this drug policy. Hearing about both positive and negative experiences with this drug plan will assist government, professional associations and others who must make decisions about drug plan policies.

You are one of a small group of pharmacists who have been selected to give their opinion on this policy. Your name was drawn randomly from a list of all practicing community pharmacists in Alberta that was provided by The Alberta Pharmaceutical Association. In order that the results of this study truly represent the thinking of pharmacists in Alberta, it is important that each survey be completed and returned in the envelope provided. The survey will take approximately 10 minutes to complete. Participation in this survey is voluntary and you have the right to refuse to answer any question.

You may be assured of complete confidentiality. There are no identifying marks on the survey that can link your name to your responses. Your name will never be placed on the survey itself. The survey will be kept in a secure area accessible only by the research team for 7 years after the study is completed. If any further analysis is conducted with the study, ethical approval will be sought at that time.

I would be happy to answer any questions you may have about this study. Please call me at (780) 492-0092 or email me at cvolume@pharmacy.ualberta.ca. Alternatively, you may contact my supervisor, Dr. Karen Farris, at (780) 492-2020. If you would like a two to three page summary of the results of this study, please contact me at the above phone number or email address and I would be happy to forward that information to you at the study's conclusion.

Thank you very much for your assistance.

Sincerely,

Carlyn Volume, B.Sc. Pharm., M.Sc.
Principal Investigator

**If you have any concerns regarding the method in which this study is being conducted please contact Dr. Edward Knaus, Director of Graduate Affairs, Faculty of Pharmacy & Pharmaceutical Sciences, at (780) 492-5993.

Appendix L

Postcard Reminder

Last week, you received a questionnaire seeking your opinions about Alberta Human Resources and Employment (formerly Alberta Family and Social Services) drug plan changes. Your name was drawn randomly from a list of community pharmacists in the province of Alberta.

If you have already completed and returned the questionnaire to us, please accept our sincere thanks. If not, please do so today. We are especially grateful for your help because we believe that your response will be very useful in evaluating the impact of the Social Services drug policy changes and will be helpful to policy makers in the future.

If you did not receive a questionnaire, or if it was misplaced, please call us at (780) 432-0729 or email us at cvolume@pharmacy.ualberta.ca and we will get another one in the mail to you today.

Sincerely,

Carlyn I. Volume, B.Sc. Pharm., M.Sc.
Principal Investigator
Faculty of Pharmacy & Pharmaceutical Sciences
University of Alberta

Appendix M

Modified Survey Cover Letter

April 21, 2000

Dear «first_name»,

About three weeks ago we wrote to you seeking your opinions on Alberta Human Resources and Employment (formerly, Alberta Family and Social Services) drug plan changes. If you have already sent in the completed survey, we would like to thank you for your help. If you have not yet sent in your completed survey, please mail it in to us as soon as possible. We have enclosed another copy of the survey along with an addressed postage paid envelope for your convenience.
This study is being conducted to gather Alberta pharmacists' opinions about Social Services drug policy changes. We are writing again because the study's usefulness depends on our receiving a survey from each respondent. You may be assured of complete confidentiality. There are no identifying marks on the survey that can link your name to your responses. Your name will never be placed on the questionnaire itself.

I would be happy to answer any questions you may have about this study. Please call me at (780) 492-0092 or email me at cvolume@pharmacy.ualberta.ca.

Thank you very much for your assistance.

Sincerely,

Carlyn Volume, B.Sc. Pharm., M.Sc.
Principal Investigator
Faculty of Pharmacy & Pharmaceutical Sciences

Appendix N

The Model Building Process

Appendix N- Determining an appropriate time series model.

68:20:92 – Misc.Anti-diabetic agents
Number of prescriptions per 100 recipients.

Defining the model:

The time series process was assumed to be the outcome of two components that include the stochastic component of the ARIMA model and a deterministic effect of an intervention component. In this case the implementation of the $2.00 copayment in November 1997 was expected to generate an abrupt and constant change in utilization of sulfonylureas, therefore the utilization parameters were assigned values of 0 prior to the intervention and values of 1 after the intervention was implemented. This is called a step function or a transfer function and denotes that the effect of the intervention will continue after its implementation.

Prior to the policy being implemented, patients were allowed to obtain up to 100 days supply of medication each time their prescription was filled. For this reason it was expected that patients would be likely to revisit their respective pharmacies for refills of their medication within a three month window of the policy being implemented. For this reason, series were differenced by a period of three to accommodate for the fact that an effect in policy may not be seen for up to three months.

The first step in selecting the appropriate time series model was a preliminary analysis that involved examination of the series to gain an overall impression about the trend in utilization occurring pre and post-policy implementation. A general estimate of changes during the time the policy was implemented was determined by calculating the mean of the series pre and pos-policy implementation. In this manner, a general impression about the impact of the policy was created and further statistical examination of whether the policy had indeed a significant impact on the utilization of sulfonylureas could be determined.

The next step in model building is the formal statistical analysis of the series. This process is outlined in the following section and pertinent output is attached for further information. The first procedure in building an appropriate time series model is identification. Involved in this process is the examination of the autocorrelation plot of the data to determine whether the series was stationary or required differencing. As stated earlier, the series was difference by a period of three to accommodate for a potential three month window in policy effect due to the 100 days supply limits. Review of the autocorrelation plot indicates that the process is now stationary therefore further differencing is not required. The autocorrelation plot also indicates that seasonal differencing is not required in the model. Examination of the partial autocorrelations an autoregressive factor is required; therefore an autoregressive filter (p=1) is used. At this point the cross-correlation of the pre-whitened series is completed to incorporate the intervention component into consideration in the model.

Model estimation was then attempted. For clarity of presentation of this example of model building strategy, two estimates of the model are provided to show the reader how possibilities were attempted and how the most appropriate model was selected from these possibilities. The estimation and diagnostic checking stage of the model building process may be repeated several times in an effort to identify the best fitting model.

The first model attempted was a simple model that examined the impact of the policy at a lag of 3 (e.g., 3$x specified in the SAS program). Several components of the output are important to note. First, the conditional least squares estimate of the model parameters is provided. Examination of these statistics indicates that the model parameters are non-significant. Another pertinent component of the model to consider are the AIC (Akaide's information criteria) and the autocorrelation check of residuals. The AIC provides information on the fit of the model and the lower the AIC, the better the model is. Another component of the output is the autocorrelation check of residuals. This diagnostic test suggests that the residual series is white noise.

The second model that was attempted was a lag of 3 (e.g., 3$(1)x is the SAS output). The output on this model would suggest that it is a better model than the previous one because the residuals are non-significant and the AIC is lower than that of the previous model. The conditional least squares estimation of the model indicates that the selected parameters are significant therefore, this model was selected.

```
                      average number of rx/100 people[redacted]  1
                        (antidiabetic agents - 682092)
                                                  19:20 Saturday, September 22, 2001

                                 The ARIMA Procedure

ARNING: The value of NLAG is larger than 25% of the series length. The asymptotic approximations
        used for correlation based statistics and confidence intervals may be poor.


                                Name of Variable = x

                 Period(s) of Differencing                         3
                 Mean of Working Series                     0.083333
                 Standard Deviation                         0.276385
                 Number of Observations                           36
                 Observation(s) eliminated by differencing         3


                                  Autocorrelations

 Lag    Covariance    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1      Std Error

   0      0.076389        1.00000    |                   |********************|             0
   1      0.048418        0.63384    |            .      |*************       |      0.166667
   2      0.020448        0.26768    |          .        |*****   .           |      0.223824
   3    -0.0075231         -.09848   |          .      **|        .           |      0.232547
   4    -0.0077160         -.10101   |          .      **|        .           |      0.233702
   5    -0.0079090         -.10354   |          .      **|        .           |      0.234912
   6    -0.0081019         -.10606   |          .      **|        .           |      0.236176
   7    -0.0082948         -.10859   |          .      **|        .           |      0.237495
   8    -0.0084877         -.11111   |         .       **|         .          |      0.238870
   9    -0.0086806         -.11364   |         .       **|         .          |      0.240302
  10    -0.0088735         -.11616   |         .       **|         .          |      0.241790

                           "." marks two standard errors


                            Inverse Autocorrelations

           Lag    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1

             1       -0.48791    |         **********|      .             |
             2       -0.32931    |            *******|      .             |
             3        0.64345    |            .      |*************       |
             4       -0.29610    |            .******|      .             |
             5       -0.18344    |            .  ****|      .             |
             6        0.33438    |            .      |*******             |
             7       -0.13885    |            .   ***|      .             |
             8       -0.06763    |            .     *|      .             |
             9        0.10756    |            .      |**    .             |
            10       -0.03380    |            .     *|      .             |
            average number of rx/100 people [redacted] 2
             (antidiabetic agents - 682092)
                                        19:20 Saturday, September 22, 2001

                         The ARIMA Procedure

                       Partial Autocorrelations

  Lag    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1

    1        0.63384     |            .      |*************       |
    2       -0.22411     |            .  ****|      .             |
    3       -0.28884     |            .******|      .             |
    4        0.29207     |            .      |******.             |
    5       -0.15826     |            .   ***|      .             |
    6       -0.18801     |            .  ****|      .             |
    7        0.17148     |            .      |***   .             |
    8       -0.13297     |            .   ***|      .             |
    9       -0.15337     |            .   ***|      .             |
   10        0.10415     |            .      |**    .             |


                 Autocorrelation Check for White Noise

  To      Chi-             Pr >
 Lag    Square     DF     ChiSq    --------------------Autocorrelations--------------------

   6     20.41      6    0.0023     0.634     0.268    -0.098    -0.101    -0.104    -0.106
```

```
          [redacted] average number of rx/100 people [redacted] 3
                  (antidiabetic agents - 682092)
                                      19:20 Saturday, September 22, 2001

                        The ARIMA Procedure

                 Conditional Least Squares Estimation

                             Standard                 Approx
Parameter      Estimate         Error    t Value    Pr > |t|     Lag

MU              0.07048       0.09275       0.76      0.4526       0
AR1,1           0.63649       0.13264       4.80      <.0001       1


              Constant Estimate      0.025619
              Variance Estimate      0.048278
              Std Error Estimate     0.219723
              AIC                    -5.00199
              SBC                    -1.83496
              Number of Residuals          36
          * AIC and SBC do not include log determinant.


                  Correlations of Parameter
                          Estimates

              Parameter          MU      AR1,1

              MU              1.000     -0.049
              AR1,1          -0.049      1.000


                 Autocorrelation Check of Residuals

 To        Chi-             Pr >
Lag      Square     DF     ChiSq     --------------------Autocorrelations--------------------

  6        7.89      5    0.1625     0.142     0.061    -0.408    -0.021    -0.021    -0.021
 12        8.05     11    0.7088    -0.022    -0.022    -0.023    -0.023    -0.023    -0.024
 18        8.35     17    0.9586    -0.024    -0.025    -0.052    -0.020    -0.014     0.008
 24        8.38     23    0.9976    -0.014    -0.009     0.007     0.006     0.006     0.005


                       Model for variable x

             Estimated Mean                0.070476
             Period(s) of Differencing            3


                      Autoregressive Factors

                   Factor 1:  1 - 0.63649 B**(1)
                  [redacted] average number of rx/100 people [redacted]          4
                          (antidiabetic agents - 682092)
                                                 19:20 Saturday, September 22, 2001

                                The ARIMA Procedure

RNING: The value of NLAG is larger than 25% of the series length. The asymptotic approximations
       used for correlation based statistics and confidence intervals may be poor.


                             Name of Variable = numrxave

               Period(s) of Differencing                              3
               Mean of Working Series                          2.527778
               Standard Deviation                              4.536801
               Number of Observations                                36
               Observation(s) eliminated by differencing              3


                                  Autocorrelations

 Lag    Covariance    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1       Std Error

   0     20.582562        1.00000    |                    |********************|              0
   1      9.571738        0.46504    |                .   |*********           |       0.166667
   2      2.961377        0.14388    |               .    |***    .            |       0.199480
   3     -0.711484        -.03457    |               .   *|       .            |       0.202342
   4      0.577846        0.02807    |               .    |*      .            |       0.202506
   5      0.947424        0.04603    |               .    |*      .            |       0.202614
   6     -3.405221        -.16544    |               . ***|       .            |       0.202905
   7     -2.597372        -.12619    |               . ***|       .            |       0.206618
   8     -7.223165        -.35094    |               .*******|    .            |       0.208748
   9     -9.458526        -.45954    |              *********|     .           |       0.224539
  10     -8.123671        -.39469    |             . ********|      .          |       0.249299

                           "." marks two standard errors


                              Inverse Autocorrelations

                 Lag    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1

                   1       -0.37108    |              *******|      .            |
                   2       -0.06712    |              .     *|      .            |
                   3        0.31980    |              .      |******.            |
                   4       -0.14641    |              .   ***|      .            |
                   5       -0.18446    |              .  ****|      .            |
                   6        0.34638    |              .      |*******            |
                   7       -0.20756    |              .  ****|      .            |
                   8        0.05571    |              .      |*     .            |
                   9        0.17180    |              .      |***   .            |
                  10        0.01445    |              .      |      .            |
                   average number of rx/100 people [redacted] 5
                     (antidiabetic agents - 682092)
                                              19:20 Saturday, September 22, 2001

                            The ARIMA Procedure

                         Partial Autocorrelations

        Lag    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1

          1        0.46504     |                .    |*********          |
          2       -0.09236     |                .  **|   .               |
          3       -0.08327     |                .  **|   .               |
          4        0.11831     |                .    |**  .              |
          5       -0.00570     |                .    |   .               |
          6       -0.27261     |               . *****|   .              |
          7        0.10654     |                .    |**.                |
          8       -0.40197     |              ********|   .              |
          9       -0.30756     |               .******|   .              |
         10       -0.02404     |                .    |   .               |


                 Autocorrelation Check for White Noise

  To       Chi-            Pr >
  Lag     Square    DF    ChiSq    --------------------Autocorrelations--------------------

    6      10.71     6   0.0977     0.465     0.144    -0.035     0.028     0.046    -0.165


                     Correlation of numrxave and x

             Number of Observations                      33
             Variance of transformed series numrxave   40.85855
             Variance of transformed series x          0.049496

                     Both series have been prewhitened.


                            Crosscorrelations

   Lag   Covariance    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1

   -10    -0.144853       -.10186      |                .  **|   .               |
    -9    -0.147866       -.10398      |                .  **|   .               |
    -8     0.149996       0.10548      |                .    |**  .              |
    -7     0.638270       0.44883      |                .    |*********          |
    -6     0.066524       0.04678      |                .    |*   .              |
    -5    -0.083272       -.05856      |                .   *|   .               |
    -4    -0.701421       -.49323      |          **********|   .               |
    -3    -0.182766       -.12852      |                . ***|   .               |
    -2    -0.193594       -.13613      |                . ***|   .               |
    -1     0.229195       0.16117      |                .    |***  .             |
     0     0.329171       0.23147      |                .    |***** .            |
     1    -0.037741       -.02654      |                .   *|   .               |
                         average number of rx/100 people [redacted]                    6
                           (antidiabetic agents - 682092)
                                                     19:20 Saturday, September 22, 2001

                                 The ARIMA Procedure

                                  Crosscorrelations

    Lag    Covariance    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1

      2     -0.307398       -.21616     |             .  ****|      .             |
      3     -0.428562       -.30136     |             .******|      .             |
      4      0.295854       0.20804     |             .      |****  .             |
      5      0.278688       0.19597     |             .      |****  .             |
      6      0.325291       0.22874     |             .      |***** .             |
      7     -0.141154       -.09926     |             .    **|      .             |
      8      0.141168       0.09927     |             .      |**    .             |
      9     -0.116124       -.08166     |             .    **|      .             |
     10     -0.104191       -.07327     |             .     *|      .             |

                             "." marks two standard errors


                        Crosscorrelation Check Between Series

 To        Chi-              Pr >
 Lag      Square     DF      ChiSq     -------------------Crosscorrelations------------------

   5        9.03      6     0.1721      0.231    -0.027    -0.216    -0.301     0.208     0.196

                  Both variables have been prewhitened by the following filter:

                                 Prewhitening Filter


                                Autoregressive Factors

                             Factor 1:  1 - 0.63649 B**(1)
ifferencing done with periods = 3.
```

```
              average number of rx/100 people [redacted] 7
               (antidiabetic agents - 682092)
                                           19:20 Saturday, September 22, 2001

                          The ARIMA Procedure

                   Conditional Least Squares Estimation

                              Standard                 Approx
Parameter       Estimate         Error    t Value    Pr > |t|     Lag    Variable     Shift

MU               3.05556       1.09286       2.80      0.0085       0    numrxave         0
NUM1            -1.05556       1.54554      -0.68      0.4993       0    x                3


                     Constant Estimate      3.055556
                     Variance Estimate      21.49837
                     Std Error Estimate     4.636633
                     AIC                     214.553
                     SBC                    217.7201
                     Number of Residuals          36
                 * AIC and SBC do not include log determinant.


                   Correlations of Parameter Estimates

                   Variable                numrxave          x
                   Parameter                     MU       NUM1

                   numrxave        MU         1.000     -0.707
                   x             NUM1        -0.707      1.000


                    Autocorrelation Check of Residuals

 To        Chi-             Pr >
Lag      Square     DF     ChiSq    --------------------Autocorrelations--------------------

  6       11.09      6    0.0858     0.464     0.146    -0.040     0.010     0.025    -0.194
 12       37.65     12    0.0002    -0.155    -0.374    -0.463    -0.375    -0.037     0.064
 18       43.81     18    0.0006     0.005    -0.104     0.026     0.172     0.136     0.166
 24       47.14     24    0.0032     0.010     0.028    -0.061     0.047     0.144     0.067


                     Autocorrelation Plot of Residuals

Lag    Covariance    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1      Std Error

  0     21.498366        1.00000    |                    |********************|             0
  1      9.970497        0.46378    |                .   |*********           |      0.166667
  2      3.148511        0.14645    |                .   |***     .           |      0.199317
  3     -0.858115        -.03992    |                .  *|        .           |      0.202284
  4      0.218591        0.01017    |                .   |        .           |      0.202503
  5      0.538762        0.02506    |                .   |*       .           |      0.202517
  6     -4.172113        -.19407    |                .****|       .           |      0.202603
```

```
                    average number of rx/100 people                                        8
                     (antidiabetic agents - 682092)
                                                     19:20 Saturday, September 22, 2001

                                  The ARIMA Procedure

                            Autocorrelation Plot of Residuals

Lag    Covariance    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1      Std Error

  7     -3.325799        -.15470    |           .    ***|       .           |      0.207703
  8     -8.046478        -.37428    |           .*******|       .           |      0.210879
  9     -9.956699        -.46314    |          *********|        .          |      0.228588
 10     -8.071169        -.37543    |         . ********|         .         |      0.253316

                              "." marks two standard errors


                               Inverse Autocorrelations

                Lag    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1

                  1       -0.36257    |            *******|      .            |
                  2       -0.06155    |            .     *|      .            |
                  3        0.32376    |            .      |******.            |
                  4       -0.13731    |            .   ***|      .            |
                  5       -0.17735    |            .  ****|      .            |
                  6        0.35238    |            .      |*******            |
                  7       -0.20075    |            .  ****|      .            |
                  8        0.06031    |            .      |*     .            |
                  9        0.17674    |            .      |****  .            |
                 10        0.00998    |            .      |      .            |


                               Partial Autocorrelations

                Lag    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1

                  1        0.46378    |            .      |*********          |
                  2       -0.08745    |            .    **|      .            |
                  3       -0.09400    |            .    **|      .            |
                  4        0.10289    |            .      |**    .            |
                  5       -0.01046    |            .      |      .            |
                  6       -0.29222    |            .******|      .            |
                  7        0.09215    |            .      |**    .            |
                  8       -0.40373    |           ********|      .            |
                  9       -0.30711    |            .******|      .            |
                 10       -0.01651    |            .      |      .            |
                       average number of rx/100 people                              9
                        (antidiabetic agents - 682092)
                                                   19:20 Saturday, September 22, 2001

                                 The ARIMA Procedure

                    Crosscorrelation Check of Residuals with Input x

 To        Chi-             Pr >
Lag      Square     DF     ChiSq     --------------------Crosscorrelations------------------

  5        6.82      6    0.3382    -0.412    -0.130    -0.088     0.038    -0.004     0.102
 11       11.42     12    0.4932     0.039    -0.097     0.219     0.037     0.154    -0.236
 17       14.97     18    0.6640     0.006     0.219     0.190     0.091    -0.122    -0.012
 23       15.00     24    0.9208    -0.014    -0.010    -0.018    -0.011    -0.010    -0.009


                             Model for variable numrxave

                        Estimated Intercept          3.055556
                        Period(s) of Differencing           3


                                   Input Number 1

                        Input Variable                      x
                        Shift                               3
                        Overall Regression Factor    -1.05556
```

```
                         average number of rx/100 people                          10
                        (antidiabetic agents - 682092)
                                              19:20 Saturday, September 22, 2001

                              The ARIMA Procedure

                       Conditional Least Squares Estimation

                            Standard                 Approx
Parameter      Estimate        Error    t Value    Pr > |t|     Lag    Variable     Shift

MU              3.35294      1.02878       3.26      0.0027       0    numrxave         0
NUM1          -12.35294      4.36475      -2.83      0.0080       0    x                3
NUM1,1        -11.64706      4.36475      -2.67      0.0119       1    x                3


                        Constant Estimate      3.352941
                        Variance Estimate      17.99265
                        Std Error Estimate     4.241774
                        AIC                     203.338
                        SBC                     208.004
                        Number of Residuals          35
                     * AIC and SBC do not include log determinant.


                         Correlations of Parameter Estimates

                     Variable           numrxave          x          x
                     Parameter                MU       NUM1     NUM1,1

                     numrxave      MU      1.000     -0.236      0.000
                     x           NUM1     -0.236      1.000      0.944
                     x         NUM1,1      0.000      0.944      1.000


                          Autocorrelation Check of Residuals

 To        Chi-             Pr >
Lag      Square     DF     ChiSq     -------------------Autocorrelations------------------

  6        9.00      6    0.1738     0.335     0.133    -0.072    -0.130     0.042    -0.260
 12       18.78     12    0.0941    -0.217    -0.186    -0.300    -0.057    -0.146     0.050
 18       21.08     18    0.2754     0.031    -0.050     0.103     0.078     0.040     0.108
 24       26.51     24    0.3276    -0.045     0.020    -0.085     0.027     0.192     0.067
```

3#(1)x

```
                                 average number of rx/100 people [redacted] 11
                                  (antidiabetic agents - 682092)
                                                  19:20 Saturday, September 22, 2001

                                      The ARIMA Procedure

                                 Autocorrelation Plot of Residuals

Lag    Covariance    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1      Std Error

  0     17.992647        1.00000    |                    |********************|             0
  1      6.025303        0.33488    |             .      |*******             |      0.169031
  2      2.401492        0.13347    |             .      |***   .             |      0.187028
  3     -1.299524        -.07223    |            .      *|       .            |      0.189730
  4     -2.347967        -.13050    |            .    ***|       .            |      0.190514
  5      0.759840        0.04223    |            .       |*      .            |      0.193051
  6     -4.683824        -.26032    |            .  *****|       .            |      0.193315
  7     -3.901384        -.21683    |            .   ****|       .            |      0.203084
  8     -3.354239        -.18642    |            .   ****|       .            |      0.209594
  9     -5.399005        -.30007    |           .  ******|        .           |      0.214279
 10     -1.020978        -.05674    |           .       *|        .           |      0.225966

                                 "." marks two standard errors


                                    Inverse Autocorrelations

                Lag    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1

                  1       -0.30997    |             .******|      .             |
                  2       -0.15032    |             .   ***|      .             |
                  3        0.35298    |             .      |*******             |
                  4        0.00375    |             .      |      .             |
                  5       -0.25459    |             . *****|      .             |
                  6        0.30013    |             .      |******.             |
                  7        0.04581    |             .      |*     .             |
                  8       -0.14575    |             .   ***|      .             |
                  9        0.22311    |             .      |****  .             |
                 10       -0.01873    |             .      |      .             |


                                    Partial Autocorrelations

                Lag    Correlation    -1 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 1

                  1        0.33488    |             .      |*******             |
                  2        0.02402    |             .      |      .             |
                  3       -0.13962    |             .   ***|      .             |
                  4       -0.07952    |             .    **|      .             |
                  5        0.15160    |             .      |***   .             |
                  6       -0.36103    |             *******|      .             |
                  7       -0.08523    |             .    **|      .             |
                  8       -0.00807    |             .      |      .             |
                  9       -0.32210    |             .******|      .             |
                 10        0.02875    |             .      |*     .             |
                              The ARIMA Procedure

                 Crosscorrelation Check of Residuals with Input x

 To        Chi-             Pr >
Lag      Square     DF     ChiSq     --------------------Crosscorrelations------------------

  5        2.00      5    0.8491     -0.091     -0.164     -0.114      0.019     -0.023      0.116
 11        7.50     11    0.7575      0.045     -0.109      0.218      0.016      0.140     -0.301
 17       11.09     17    0.8520     -0.019      0.221      0.177      0.048     -0.168     -0.027
 23       11.09     23    0.9822     -0.005     -0.007     -0.004     -0.003     -0.003     -0.003


                         Model for variable n[illegible]xave

                     Estimated Intercept        [illegible].352941
                     Period(s) of Differenc[illegible]          3


                              Input Number [illegible]

                            Input Variable [illegible]
                            Shift              3


                              Numerator Factors

                     Factor 1:  -12.353 + 11.6471 B**(1)
```